In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

E-Filed: June 12, 2013

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JOANN MOSTOVOY and VADIM MOSTOVOY, in their own right and as best friends of their son, VJM,	*	PUBLISHED
	*	No. 02-10V
	*	Chief Special Master Campbell-Smith
Petitioners,	*	
v.	*	Discovery; Vaccine Rule 7; Original Research Study; Vaccine Safety Datalink
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * * *		

RULING CONCERNING PETITIONERS' MOTION TO SUPPLEMENT THE RECORD ON MOTIONS TO COMPEL, AND PETITIONERS' MOTION TO COMPEL ACCESS TO THE VACCINE SAFETY DATALINK, PETITIONERS' MOTION FOR AUTHORITY TO ISSUE SUBPOENA, PETITIONERS' MOTION FOR PRE-PAYMENT OF EXPERT EXPENSES, AND PETITIONERS' MOTION TO COMPEL PRODUCTION OF FDA DOCUMENTS

Pending before the undersigned are petitioners' five motions. For the reasons set forth below, the undersigned hereby grants-in-part and denies-in-part petitioners' Motion to Supplement the Record on Motions to Compel, denies petitioners' Motion to Compel Access to the Vaccine Safety Datalink, denies petitioners' Motion for Authority to Issue Subpoena, denies petitioners' Motion for Pre-Payment of Expert Expenses, and denies petitioners' Motion to Compel Production of FDA Documents.

I. INTRODUCTION

Petitioners brought a claim pursuant to the National Vaccine Injury Compensation Program (Vaccine Program or Program) on behalf of their son, VJM, in which they allege

the measles, mumps & rubella (MMR)[1] vaccine he received in January 1999 caused his pervasive developmental disorder, an autism spectrum disorder. Am. Pet. 1, ¶¶ 10, 12, 15. Petitioners' son was one year old at the time of the vaccination, Id. ¶ 1, and thereafter, petitioners allege he failed to either gain or maintain his verbal and social skills, Id. ¶ 6.

Petitioners assert, as their theory of causation, that their son had an adverse reaction to human DNA contained in the rubella portion of the MMR vaccine, which triggered his autism spectrum disorder. Id. ¶¶ 15-16; Pet'r's Ex. 10 (Deisher's expert report) ¶¶ 3, 17.

On February 3, 2012, petitioners filed several motions seeking: (1) an order to compel respondent to provide them access to the Vaccine Safety Datalink, (2) an order for authority to issue subpoenas to ten named private managed care organizations (MCOs), and (3) an order granting authorization for interim expert expenses in the estimated amount of $260,000.[2]

Petitioners seek access to data from the Vaccine Safety Datalink Project (hereafter the VSD Project) to allow their expert, Theresa A. Deisher, Ph.D., to conduct an original study comparing the rate of autism disorder incidence among children who received a particular vaccine, with the rate among children who did not receive that vaccine. As discussed more fully below, petitioners' expert does not seek to study the MMR vaccine at issue in this matter, but rather the varicella vaccine.

Because a portion of the VSD Project data is in the possession of the Centers for Disease Control and Prevention[3] (CDC) and another portion is in the possession of the ten private MCOs, petitioners filed dual motions; one to compel discovery of CDC as a party and the other to issue subpoenas to the ten MCOs as multiple non-parties.

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[1] Petitioners' son also received the Haemophilus influenzae type B (HIB) and Hepatitis (HEP) vaccines on the same date; however, petitioners' theory of causation is based solely on the MMR vaccine. Am. Pet. ¶ 16.

[2] Petitioners' Motion for Authority to Issue Subpoena, Motion to Compel Access to the Vaccine Safty Data Link [sic] and Motion for Pre-Payment of Expert Expenses, Feb. 3, 2012, ECF No. 46 (hereinafter "Pet'rs' MTC").

[3] The CDC is an operating component of the U.S. Department of Health and Human Services, the respondent in this matter.

Respondent[4] and the MCOs[5] filed separate briefs in opposition to petitioners' motions, to which petitioners filed a reply.[6] Petitioners then filed a motion to supplement the record with additional evidence in support of their motion to compel, to which both the respondent and the MCOs objected.

On March 2, 2012, petitioners filed a motion to compel production of FDA documents. Respondent filed a brief in opposition and petitioner filed a reply. On May 28, 2013, petitioners filed a status report calling the attention of the undersigned to the pending motions, and providing recent CDC information on the incidence of autism disorder.

The undersigned addresses petitioners' multiple motions, in turn, considering the motion to supplement the record first.

II. PETITIONERS' MOTION TO SUPPLEMENT THE RECORD

On November 2, 2012, petitioners moved[7] for approval to file two additional declarations in support of their motion to compel, one from their expert, Dr. Deisher, and one from the petitioner in another Vaccine Program matter,[8] Ms. Mary Ann Podraza Penzi. In addition, petitioners filed a reply brief[9] to which they attached as an exhibit the

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[4] Respondent's Response to Petitioners' Motion to Compel Access to the Vaccine Safety Datalink, Mar. 30, 2012, ECF No. 58 (hereinafter "Resp't's Resp. to MTC").

[5] Objection of Non-Party Managed Care Organizations to Petitioners' Motion for Authority to Issue Subpoena, Motion to Compel Access to the Vaccine Safety Datalink, and Motion for Pre-Payment of Expert Expenses, Mar. 30, 2012, ECF No. 60 (hereinafter "MCOs' Obj. to MTC").

[6] Petitioners' Reply to the Respondent's and HMOs' Objections to Motion to Compell [sic], Apr. 13, 2012, ECF No. 63 (hereinafter "Pet'rs' Reply re MTC").

[7] Petitioners' Motion to Supplement the Record on Motions to Compell [sic], Nov. 2, 2012, ECF No. 71 (hereinafter "Pet'rs' MTS").

[8] Penzi v. Sec'y of Health & Human Servs. (07-750V). It was not clear from either Ms. Penzi's declaration or petitioners' motion to supplement whether Ms. Penzi is seeking to intervene in the Mostovoy matter, or seeking only to have her declaration made a part of this record.

[9] Petitioners' Reply to the Respondent's and HMOs' Objections to Motion to Supplement the Record, Nov. 26, 2012, ECF No. 76 (hereinafter "Reply re MTS").

response from the National Institutes of Health (NIH) to Dr. Deisher's request for NIH funding of her research. The undersigned construes this attachment to contain an implied request to supplement the earlier motion.

The respondent[10] and MCOs[11] each filed a brief in opposition to petitioners' motion to supplement.

A. Legal Standard

Guiding the actions of special masters with the Court of Federal Claims are two sets of rules: (1) the Rules of the Court of Federal Claims (RCFC) and (2) the Vaccine Rules of the Court of Federal Claims (Vaccine Rules), found in Appendix B of the RCFC. Special masters are bound by both the RCFC and the Vaccine Rules. Vaccine Rule 1; Patton v. Sec'y of Health & Human Servs., 25 F.3d 1021, 1026-27 (Fed. Cir. 1994) (stating that the discretion afforded under Vaccine Rule 1 "may not be exercised in a manner that would disturb or exceed the framework laid out by the Court of Federal Claims pursuant to its authority under the Act").

Vaccine Program matters are governed by the Vaccine Rules, and the RCFC apply only to the extent they are consistent with the Vaccine Rules. Vaccine Rule 1. A special master retains the discretion, "[i]n any matter not specifically addressed by the Vaccine Rules, . . . [to] regulate the applicable practice, consistent with the[] [Vaccine] rules, and with the purpose of the Vaccine Act, to decide the case promptly and efficiently." Vaccine Rule 1(b).

As legal support for their request, petitioners point to RCFC 24 which addresses the issue of intervention. But the Vaccine Rules expressly address the issue of intervention providing: "No person may intervene in a vaccine injury compensation proceeding, but the special master may afford all interested individuals an opportunity to submit relevant written information within 60 days after publication of notice of the petition in the Federal Register, or later with leave of the special master." Vaccine Rule 15. Because the court's rules conflict with the Vaccine Rules on the matter of intervention, Vaccine Rule 15 controls.

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[10] Respondent's Response to Petitioners' Motion to Supplement the Record, Nov. 19, 2012, ECF No. 73 (hereinafter "Resp't's Resp. to MTS").

[11] Response of Non-Party Managed Care Organization to Petitioners' Motion to Supplement the Record on Petitioners' Motion to Compel Access to the Vaccine Safety Datalink, Nov. 20, 2012, ECF No. 75-1 (hereinafter "MCOs' Resp. to MTS").

On the matter of motions to supplement, neither the Vaccine Rules nor the RCFC specifically address the issue, although the filing of a supplemental motion has been permitted in earlier Vaccine Program cases. See, e.g., Bennett v. Sec'y of Health & Human Servs., No. 03-2067V, 2012 WL 2550836, at *2 (Fed. Cl. Spec. Mstr. Apr. 13, 2012) (allowing respondent to supplement her motion to dismiss); Carrington v. Sec'y of Health & Human Servs., No. 99-495V, 2009 WL 989399, at *1 (Fed. Cl. Spec. Mstr. Mar. 26, 2009) (considering petitioners' supplemental filing in a motion for attorney fees).

B. Filings

In her declaration, Pet'rs' Ex. 61, Dr. Deisher reports the preliminary results of a state level study she is currently conducting using data collected from each state on the varicella vaccine and autism disorder. From this study, Dr. Deisher concludes that there is a connection between the varicella vaccine and autism disorder. Previously persuaded of this connection, she had earlier applied for funding from NIH for an original research study on "Safety Study of Human DNA and HERVK Contaminants in Childhood Vaccines." Pet'rs' Ex. 62 at 1.

Respondent opposes petitioners' motion to supplement, asserting that the additional information is neither relevant nor necessary to the resolution of petitioners' motion to compel. Respondent argues that petitioners' motion to compel is an attempt to use the discovery process to facilitate litigation-driven research. Resp't's Resp. to MTS 3-4. Respondent further argues that Dr. Deisher has made no effort to follow the usual procedures for an outside researcher to gain access to the data she seeks.

With leave to file, the MCOs also responded in opposition to petitioners' motion to supplement, asserting that because Dr. Deisher has been able to access data to conduct her proposed study, the access petitioners now seek to their data is not necessary or reasonable. MCOs' Resp. to MTS 2.

Attached to petitioners' reply are the critiques provided by the three reviewers who, on behalf of the NIH, assessed Dr. Deisher's proposed study. Pet'rs' Ex. 62. To address respondent's criticism that Dr. Deisher is endeavoring to circumvent the protocol for gaining access to the data, petitioners offered the critiques as evidence that Dr. Deisher has attempted, unsuccessfully, to secure outside funding for her proposed study, and because neither she nor petitioners can afford to fund the proposed study on their own, efforts to seek access through the established process would be futile. Reply re MTS 1.

In further support of the request for VSD access, petitioners filed the declaration of Ms. Penzi. Pet'rs' Ex. 60. In her declaration, Ms. Penzi states that she has brought a representative claim in another Vaccine Program matter asserting the same theory of

causation as petitioners have asserted in this matter. Id. at ¶ 7-8. Her child received both the varicella and MMR vaccines. Id. at ¶ 3.

C. Discussion

The declaration of Dr. Deisher, Pet'rs' Ex. 61, provides information about her current work as a research scientist and points to non-VSD Project data that she asserts has enabled her to establish a connection between the varicella vaccine and autism disorder. This is relevant to the undersigned's consideration of petitioners' motion to compel.

The rejection by NIH of Dr. Deisher's request for funding, Pet'rs' Ex. 62, contains a detailed assessment by NIH reviewers of Dr. Deisher's professional credentials and her proposed study. Because the NIH reviewers bear responsibility for evaluating both research scientists and their proposed studies to determine the likelihood of the studies' success, the NIH's rejection of Dr. Deisher's request is relevant to the undersigned's consideration of petitioners' motion to compel. Thus, petitioners' motion to supplement the record is **GRANTED** with regard to petitioners' Exs. 61 and 62.

With respect to Ms. Penzi's declaration, intervention in Vaccine Program matters is not permitted under Vaccine Rule 15. To the extent petitioners seek permission for Ms. Penzi to intervene in this matter, petitioners' motion is **DENIED**. Moreover, because there is nothing in Ms. Penzi's declaration that is relevant to a consideration of petitioners' motion to compel, petitioners' motion to supplement the record with petitioners' Ex. 60 is **DENIED**.

Before turning to address petitioners' motion to compel, motion to issue subpoenas, and motion for pre-payment of expert expenses, a brief discussion of the VSD project--which contains the data Dr. Deisher wants to access--is provided for context.

III. BACKGROUND

A. Vaccine Safety Datalink Project

The VSD Project is a collaborative undertaking involving the participation of both the CDC and various MCOs. The number of participating MCOs has varied over the years from an initial group of four to the current group of ten. MCOs' Obj. to MTC 7-8.

The purpose of the VSD Project is both to monitor potential vaccine-related adverse events and to allow "large, rigorous epidemiologic studies of potentially rare adverse events" associated with vaccinations. Id. 7, 9. The participation of each MCO in the VSD Project is strictly voluntary. Id. 8.

The VSD Project contains a sizable collection of data, including "comprehensive medical and immunization histories for more than 5.5 million people annually, which are derived from the participating managed care organizations that contain more than 9 million members." Id. 7. According to Dr. Deisher, the VSD database and the U.S. Census databases contain, together, a minimum of "an annual birth cohort of 90,000 children, with a minimum of 600,000 children under age 7 enrolled at any time." Deisher's MTC Decl. ¶ 12.[12]

The VSD Project is considered a linked database because it provides access to vaccination records, patient characteristics, and health outcomes. This linked information allows the VSD "to serve as a unique and potentially powerful resource for the ongoing evaluation of vaccine safety." MCOs' Ex. C at 14.

VSD Project data collected by each MCO, and made available to the CDC, includes "select data . . . relating to members' vaccination and health histories. The data include vaccination, outpatient, inpatient, emergency-room, pharmacy, and enrollment-status information." MCOs' Obj. to MTC 8-9.

The relationship between the CDC and the MCOs is defined by contract.[13] As discussed in more detailed, infra, a significant change in this relationship occurred as of January 1, 2001.

Data sets provided by the MCOs to the CDC through December 31, 2000 are potentially available to outside researchers through a well-defined Data Sharing Program. Data sets from 2001 onward are not included in the Data Sharing Program, but are potentially available to outside researchers through each individual MCO.

1. Data Sharing Program

The Data Sharing Program is administered by a component of the CDC, the National Center for Health Statistics Research Data Center (RDC), and includes two distinct types of data:

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[12] Declaration of Theresa A. Deisher, Ph.D., filed Feb. 3, 2012 in support of Pet'rs' motion to compel (MTC), ECF No. 46-1 (Pet'rs' Ex. 46) (hereinafter "Deisher's MTC Decl.").

[13] The CDC contracts with the American Association of Health Plans, a national trade association for health insurers, which in turn contracts with some of its member MCOs who provide their data to the CDC. MCOs' Obj. to MTC 7-8.

(1) A database containing the datasets assembled by each MCO and provided to the CDC from its inception in 1990 to December 31, 2000; and

(2) Final datasets created and used for published studies from August 2002 onward.

MCOs' Obj. to MTC 10 (citing MCOs' Ex. D[14]).

Access to data requires the approval of both the CDC and the individual MCOs. MCOs' Ex. D at 20. The MCOs describe the application process for an outside researcher seeking access to data through the Data Sharing Program:

> A proposal from outside researchers to access VSD data through the Data Sharing Program is submitted to the CDC to ensure that the proposal is technically feasible and complete. The proposal is then forwarded to the IRBs [Institutional Review Boards] of each MCO whose data, which has already been created and now resides at the CDC, might be accessed. Upon IRB approval, the dataset in question is made available at the Research Data Center ("RDC") of the National Center for Health Statistics. A technical monitor is present at the RDC for the entire period during which these VSD datasets are used by outside researchers.

Id. 11; see also MCOs' Ex. D at 20-21.

2. Post-2000 VSD Project Data

As of January 1, 2001, the MCOs no longer provide the CDC with annual datasets. MCOs' Obj. to MTC 11. Rather, the MCOs continue to collect relevant data, but each MCO "owns and manages its own VSD data," in a standard format developed by the CDC and the MCOs. Id. 12. Because each MCO now retains its own VSD Project data, there is no single database housing all of the post-2000 VSD Project data.

While MCOs continue to make post-2000 VSD Project data available to outside researchers, researchers must apply directly to the IRB of each MCO whose data they wish to access, and the researcher must collaborate with a VSD project member. Id. 10, 12. These procedures apply not only to outside researchers, but also to the CDC, which cannot access any post-2000 VSD Project data for use in any study without first satisfying the IRB process and entering into a Data Use Agreement with each individual

[14] U.S. Nat'l Ctr. for Health Statistics, CDC, Procedures & Costs for Use of the Research Data Center, App. IV Vaccine Safety Datalink (VSD) Data Sharing Program (2005).

MCO. Resp't's Resp. to MTC 19. Each MCO has the sole discretion to grant or deny a request for access to its data.

B. Dr. Deisher's Work

Petitioners' expert, Dr. Deisher, holds a doctorate in molecular and cellular physiology. Deisher's CV 1.[15] Petitioners have filed four documents in this matter authored by Dr. Deisher: (1) an expert report;[16] (2) a declaration in support of petitioners' motion to compel; (3) a completed, unpublished study on changepoints in the rate of autism disorder;[17] and (4) the preliminary results of an in-progress study on the varicella vaccine and the rate of autism disorder.[18] To support petitioners' claim of vaccine-related causation, Dr. Deisher relies on both her existing work as well as her proposed VSD Project study.

In her expert report and her declaration, Dr. Deisher describes her theory that human fetal DNA in certain vaccines—including the MMR and varicella vaccines—is a trigger for autism disorder. Deisher's expert report ¶¶ 3, 17; Deisher's MTC Decl. ¶¶ 8-10. Dr. Deisher asserts that the combination of (1) the statistical work she has done in her changepoint study showing three changepoint years in the incidence of autism disorder, (2) the literature showing that autistic children have large numbers of genetic factors that they did not receive from their parents, and (3) the literature showing that DNA can be transferred from human contaminants in vaccines to the nerve cells of the recipient by injection, furnishes sound support for her theory of harm. Deisher's expert report ¶ 23.

Dr. Deisher proposes to conduct an original study to explore her hypothesis that "should residual human fetal DNA in vaccinations be related to subsequent regressive

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[15] Deisher's Curriculum Vitae filed on Dec. 20, 2011, ECF No. 45 (Pet'rs' Ex. 12) (hereinafter "Deisher's CV").

[16] Deisher's expert report, Nov. 30, 2011, ECF No. 45 (Pet'rs' Ex. 10) (hereinafter "Deisher's expert report").

[17] Marissa LaMadrid, Christopher Brown & Theresa Deisher, US Autistic Disorder (1970 – 2002) Changepoints Do Not Coincide with Changepoints for Suspected Sociologic and Environmental Causes (Mar. 16, 2011) (unpublished), ECF No. 45 (Pet'rs' Ex. 26) (hereinafter "Deisher's changepoint study").

[18] Declaration of Theresa A. Deisher, reporting the preliminary results of her state-level varicella study, Oct. 23, 2012, ECF No. 71-2 (Pet'rs' Exs. 61 & 61A) (hereinafter "Deisher's state-level varicella study").

autism disorder, the numbers of children contained in the … VSD and the gradual uptake of Varicella should be sufficient to reveal a difference between autism spectrum disorders[19] in Varicella vaccinated and non-vaccinated children" during the years 1994 to 2005." Deisher's MTC Decl. ¶ 9.

1. Dr. Deisher's Changepoint Study

Dr. Deisher reviewed data from 1970 to 2002 and identified three birth year changepoints. Dr. Deisher explained that a birth year changepoint is the year in which children subsequently diagnosed with autism disorder were born, not the year in which diagnosis of autism disorder increased. Deisher's expert report ¶ 9.

The birth year changepoints Dr. Deisher identified were 1980, 1988 and 1995. Deisher's changepoint study 1. Deisher points out that her study confirms the finding of an earlier study completed by EPA researchers in which they identified 1988 as a changepoint year.[20] Deisher's changepoint study 1; Deisher's expert report ¶ 12.

Dr. Deisher also considered certain sociologic factors that have been discussed in the literature as being potentially responsible for the increased rate at which autism disorder is diagnosed. These sociologic factors include increased professional awareness of autism disorder, increased parental awareness of autism disorder, revisions in the definition of autism disorder in the Diagnostic and Statistical Manual (DSM), federal funding for special education (requiring a diagnosis of autism disorder), and an increase in the cumulative thimerosal load in vaccines. Deisher's changepoint study 4, 7, 10. Dr. Deisher devised methods to identify a changepoint for each factor, that is, to identify the year in which a change occurred in a sociologic factor that could affect the rate at which autism disorders are diagnosed. Id. 4.

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[19] Dr. Deisher appears to have misspoken in this reference to autism spectrum disorders because she has repeatedly stated she is considering only autistic disorder, not autism spectrum disorder. Deisher's changepoint study 15; Deisher's expert report ¶ 9; Deisher's MTC Decl. ¶ 13; Deisher's state-level varicella study ¶ 5.

[20] EPA researchers identified changepoint years of 1987 and 1988, using two different data sets. In a third dataset (1988-1996), the EPA researchers found no changepoint because the incidence of autism increased steadily during that time frame. M.E. McDonald & J.F. Paul, Timing of Increased Autistic Disorder Cumulative Incidence, 44 Envtl. Sci. & Tech. 2112, 2113 (2010) (both authors were employed by the National Health and Environmental Effects Research Laboratory, U.S. Environmental Protection Agency) (Pet'rs' Ex. 27).

Dr. Deisher then compared each of the sociologic factor changepoints to the three changepoints for autism disorder that she had identified. Because she found no matches, she concluded that these sociologic factors were not responsible for the observed increase in autism disorder. Id. 12-18.

Dr. Deisher concluded her study by recommending further study to identify the reasons for the increase in autism disorder. Id. 18.

2. Dr. Deisher's Expert Report

Dr. Deisher theorizes that each of the three birth year changepoints she identified in her changepoint study can be attributed to a vaccine manufactured using human fetal cell lines. Deisher's expert report ¶ 9. She explains that there are nine vaccines manufactured with human fetal cell lines, of which only three, the varicella, hepatitis A and MMR II vaccines, were introduced during the time period of her changepoint study, 1970-2002. Id. ¶ 17. Thus, the effect on the rate of autism disorder, if any, of the remaining six vaccines was not captured in Dr. Deisher's study. [21]

Dr. Deisher points to the time periods within which the changes in the MMR vaccine occurred and the varicella vaccine received approval. She asserts that these events can be linked to the three autism disorder changepoints she has identified. She attributes both the 1981 and 1988 changepoints to changes in the MMR vaccine, and the 1995 changepoint to the approval process for the varicella vaccine. Id. ¶ 20.

To explain the 1981 observed changepoints in the MMR vaccine, Dr. Deisher posits that: (1) a change in the manufacturing method for the rubella portion of the MMR vaccine was approved in 1979 to allow production in "human fetal [tissue]" and (2) by 1983, the MMR vaccine manufacturer held a market monopoly, but she provides no authority for these assertions. Id. Dr. Deisher contends that these factors coincided with the 1981 autism disorder birth year changepoint. Deisher's expert report ¶ 20; Deisher's MTC Decl. ¶ 9.

Dr. Deisher states that in 1989, a second dose of MMR was added to the childhood immunization schedule. Although recommended for administration shortly before a child enters school, the second MMR vaccine could be given once a 28-day period following the first dose had elapsed. Deisher's expert report ¶ 20. Dr. Deisher attached particular significance to a vaccine compliance campaign--initiated after measles outbreaks in 1988

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[21] According to Dr. Deisher, the remaining six vaccines are the ProQuad (chickenpox and MMR), Vaqta (Hepatitis A), Twinrix (Hepatitis A and Hepatitis B), Pentacel (Polio and DTaP, and HiB), Imovax (Rabies) and Zostavax (Shingles). Deisher's expert report ¶ 17.

and 1989--that raised compliance from "as low as 62.2%," between 1986 and 1989 to over 82% in 1991. Yet, she provided no authority for her assertions about either the second dose of MMR vaccine or the post-measles compliance campaign. (The compliance rates appear to be taken from Pet'rs' Ex. 35.) Dr. Deisher correlated the improved vaccine compliance with the 1988 autism disorder birthyear changepoint. Deisher's expert report ¶ 20; Deisher's MTC Decl. ¶ 9.

Finally, Dr. Deisher observed that the varicella vaccine was approved for use in the United States in 1995, and uptake of that vaccine was gradual between 1996 and 2005. Deisher's expert report ¶ 20; Deisher's MTC Decl. ¶ 9. Dr. Deisher contends that the introduction of the varicella vaccine coincides with the 1995 autism disorder birth year changepoint. Deisher's expert report ¶ 20; Deisher's MTC Decl. ¶ 9.

Dr. Deisher maintains that she has ruled out other possible causes of the increase in the diagnosis of autism disorder that have been discussed in the scientific literature, particularly, the sociologic factors. She avers that she now has discovered a temporal link between the changes in the MMR vaccine and the introduction of the varicella vaccine that correspond to the birth year changepoints in the incidence of autism disorder she has identified. Based on her findings, Dr. Deisher contends that it is "far more likely than not" that the use of human cell lines in the manufacturing method of the MMR and varicella vaccines is the trigger that resulted in the observed increase in autism disorder. Deisher's expert report ¶ 28.

3. Dr. Deisher's State-Level Varicella Study

Petitioners filed the preliminary results of an additional study undertaken by Dr. Deisher, in which she purportedly "used data maintained by each state, the CDC[22] and the US Department of Education to compare the [receipt] of varicella [vaccine with the] autism disorder prevalence in each state and in the United States overall." Deisher's state-level study ¶ 6.

After plotting varicella vaccine administrations against state reports of autism diagnosis by birth year, Dr. Deisher has concluded that there is a "direct correlation between the use of Varicella vaccine and diagnosis with autism disorder for each birth year between 1992 and 1998," that is evident in 44 out of the 50 states. Id. ¶¶ 7, 8.

Dr. Deisher attributes the increase in autism disorder between the birth years 1980 and 1992 to both the MMR II vaccine and an "increased Thimerosal load in vaccines." She attributes the increase in autism disorder thereafter--from birth years 1992 through 1998--to the introduction of the varicella vaccine.

[22] It is unclear what CDC data Dr. Deisher used.

Dr. Deisher acknowledges that the "rise in diagnosis" for autism disorder continued after the uptake of the varicella vaccine reached a plateau, in birth year 1998 and thereafter (described by Dr. Deisher as "1998 on").[23] She further acknowledges that this "rise" may not be a real increase in the rate of autism disorder, but rather an increase in the diagnosis rate of the disorder possibly resulting from increased parental and health professional awareness of autism disorder and increased federal funding for special education. Id. ¶¶ 9, 11.

4. Dr. Deisher's Opinion in Support of Petitioners' Theory

Dr. Deisher contends that her data show that "some widespread, perhaps almost universal, exposure or environmental trigger" affected children born in and after, the changepoint years, 1981, 1988 and 1996.[24] Deisher's expert report ¶ 12. This exposure or environmental trigger could have occurred either in utero, or at any time between birth and three years of age, which is the time period during which an autism disorder is generally diagnosed. Deisher's expert report ¶ 9, 12; Deisher's MTC Decl. ¶ 8.

Dr. Deisher expects her proposed VSD study to yield findings that will support her theory that the introduction of the varicella vaccine led to the 1995 autism disorder changepoint she has observed. She explains that the varicella vaccine is likely an environmental trigger for ASDs due to the method of its manufacture, which is the same manufacturing method used for the MMR vaccine. Proof of her theory concerning the varicella vaccine would support petitioners' theory that the manufacturing method used to produce the MMR vaccine that their son received was causally responsible for his development of regressive autism spectrum disorder. As Dr. Deisher stated in her expert report:

> **[A]s our research has eliminated all other causes currently used to challenge vaccine causation** and has established a temporal link …which could explain causation … it is far more likely than not **that the use of human cell lines in the manufacture of vaccines caused a significant**

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[23] Dr. Deisher makes reference to "1998 on," but it is unclear whether she is referring to the endpoint of her changepoint study in 2002, or to the present. If the reference is to the present, it is unclear why Dr. Deisher attributes none of the continuing increase in autism incidence to the six additional vaccines introduced after 2002 and manufactured by the same method as the varicella and MMR vaccines.

[24] Dr. Deisher's third changepoint year is 1995.6. Deisher's changepoint study 1. She treats this change point year inconsistently, sometimes rounding down to 1995, and sometimes rounding up to 1996.

> **increase in the incidence of neurological damage in vaccinated children**, giving rise to clinical symptoms which are within the DSM construct for Autism.

Deisher's expert report ¶ 28 (emphasis added).

IV. LEGAL STANDARD

A. The Relevant Statutory Provisions and Court Rules[25]

The Vaccine Act contains provisions that address discovery in Vaccine Program cases. The statute compels the Court to adopt rules that "provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims." 42 U.S.C. § 300aa-12(d)(2)(E). The Vaccine Act further provides that a special master:

> (i) may require such evidence as may be reasonable and necessary,
> (ii) may require the submission of such information as may be reasonable and necessary, [and]
> (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary.

§ 300aa-12(d)(3)(B).

In turn, the Court has promulgated the "Vaccine Rules," Rule 7 of which pertains to discovery. It states, in relevant part:

> Rule 7. Discovery.
>
> (a) In General. There is no discovery as a matter of right. The informal and cooperative exchange of information is the ordinary and preferred practice.
>
> (b) Formal Discovery.

[25] Citing to a 2011 decision in the Paluck case, petitioners argue that their standard of proof in this court is now more than a preponderance of the evidence. Pet'rs' MTC 9-12 (citing Paluck v. Sec'y of Health & Human Servs., No. 07-889, 2011 WL 6949326 (Fed. Cl. Spec. Mstr. Dec. 14, 2011), vacated, 104 Fed. Cl. 457 (2012)). Because the Paluck decision was vacated, any discussion of petitioners' interpretation of that decision is unnecessary.

(1) *By Motion.* If a party believes that informal discovery is not sufficient, the party may move the special master . . . to employ any of the discovery procedures set forth in RCFC 26–37.
(2) *Contents of the Motion.* The moving party must indicate the discovery sought and state with particularity and the reasons therefor, including an explanation as to why informal discovery techniques have not been sufficient.

(c) Subpoena. On the request of a party, the special master may approve the issuance of a subpoena pursuant to RCFC 45.

Vaccine Rule 7

The plain language of the Vaccine Act provides a special master with the authority to "require" testimony, or "require" the submission of "evidence" or "information" or "documents," whenever that master deems such testimony, evidence, information, or documents to be "reasonable and necessary" for the master's resolution of a Vaccine Act case. This statutory authority is implemented by Vaccine Rule 7, which authorizes a special master--when that master deems it "necessary"-- to (1) use the formal discovery procedures of RCFC 26-37, and (2) authorize a party to issue subpoenas, utilizing the procedures of RCFC 45.

Stating that a special master "may require the testimony of <u>any</u> person and the production of <u>any</u> documents as may be reasonable and necessary," the Vaccine Act plainly extends the special master's authority to "require" testimony and submission of evidence to <u>non-parties</u> as well as parties in a Program proceeding, § 300aa-12(d)(3)(B)(iii) (emphasis added).

This broadly conferred statutory authority has been incorporated into the Court's vaccine rules. Vaccine Rule 7(c) provides that special masters may approve the use of subpoenas under the procedures of RCFC 45 and RCFC 45(c). Rule 45(c) provides for the service of subpoenas on "persons," not just parties.

B. Discovery in Vaccine Act Litigation Is Unlike Discovery in Other Federal Litigation

The statutorily conferred "discovery" authority given to a special master in the context of vaccine proceedings is distinguishable from the discovery allowed in most legal proceedings. The differences are two-fold.

First, as briefly discussed below, the basic purpose for discovery under the Vaccine Act is different. In most other litigation, a <u>party</u> seeks information to present to the factfinder and the judge's role in such discovery proceedings is merely to <u>referee</u>

disputes concerning whether the requested discovery is appropriate within the prescribed discovery rules and precedents. Contrastingly, in the Vaccine Act context, the special master not only referees procedural disputes, but also serves as the ultimate factfinder on all disputed factual issues. Thus, when a special master is deciding whether to exercise her discovery authority, she must determine whether the production of the material in question is "reasonable and necessary" to her own resolution of the factual issues in dispute. In other words, when a special master contemplates whether to require testimony or submission of evidence, the special master: (1) must evaluate the importance and relevance of the material in question based on the overall context of the factual issues to be decided, (2) must determine whether the material is necessary to reach a fair and well-informed decision concerning those factual issues, and (3) must consider whether it is reasonable to require the production of the material.

Second, in Vaccine Act cases, the standard for determining whether to require testimony or document production is notably different from the standard applied in other litigation discovery disputes. Both the RCFC and the Federal Rules of Civil Procedure provide that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense . . . ." RCFC 26(b)(1) (emphasis added); Fed. R. Civ. P. 26(b)(1). Thus, the test in the Court of Federal Claims, and other federal courts, is simply whether the material sought is relevant to the issues in the case.

In contrast, in Vaccine Act cases, the test is whether the special master finds that the material sought is necessary and reasonable to the master's resolution of contested issues. As the ordinary meanings of the words "relevant" and "necessary" indicate, material could be "relevant" to an issue without being "necessary" to the resolution of that issue. Therefore, it seems that the Vaccine Act imposes a substantially higher standard for the issuance an order to compel discovery.

C. Necessary and Reasonable

As discussed above, the Vaccine Act's use of the terms "necessary" and "reasonable" indicates that the special master must apply a more rigorous standard than the "relevance" test generally used in other litigation when deciding whether to "require" testimony or document production.

1. Necessary

Special masters have considered and addressed how much stricter the necessary standard is than the relevance standard. The imposition of a standard that would allow a finding that material is necessary only if rendering a decision would be absolutely impossible without it has been deemed too strict. See In re: Omnibus Autism

Proceeding[26] 2007 WL 1983780, at *7 (Fed. Cl. Spec. Mstr. May 25, 2007). In rejecting this standard as unduly restrictive, the special masters reasoned that such a standard could

> *never* be met, since a factfinder in a legal case can *always* rule on a factual issue no matter how scanty the evidence, even in the absence of *any* evidence. That is, in legal factfinding, if there is no evidence, the factual issue simply is resolved against the party having the "burden of proof." The "absolutely impossible" standard, therefore, plainly seems to be too strict, since under such a standard a special master would *never* require production, even of a petitioner's own medical records, and the master's statutory power to "require" testimony and the submission of evidence would amount to a nullity.

Id. at *7.

After careful consideration, the standard applied to determine whether requested material is "necessary" in vaccine proceedings is whether, based on "the overall context of the factual issues to be decided, the special master could not make a fair and well-informed ruling on those factual issues without the requested material." OAP, 2007 WL 1983780, at *7; see, e.g., Morman v. Sec'y of Health & Human Servs., No. 10–814V, 2012 WL 1901276, at *3 (Fed. Cl. Spec. Mstr. May 7, 2012); King v. Sec'y of Health & Human Servs., No. 03–584V, 2008 WL 1994968, *3 (Fed. Cl. Spec. Mstr. Feb. 7, 2008); In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder,[27] 2004 WL 1660351, at *9 (Fed. Cl. Spec. Mstr. July 16, 2004).

2. Reasonable

If production of the requested material is found to be necessary, the special master must then consider whether it is also "reasonable" under all of the circumstances. This inquiry has been construed to require that the special master consider the burden to be placed on the party or person who would bear responsibility for producing the information. OAP, 2007 WL 1983780, at *7. The importance of the requested material to the special master's ruling on the fact issues must be balanced against the burden imposed on the producing party or

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[26] The Omnibus Autism Proceeding (OAP) was a very large group of cases with common issues of medical causation. Because the OAP proceedings were a general matter, the results of which could be applied in an individual case, there is no docket number for the OAP proceeding.

[27] This was an earlier proceeding in what came to be known as the OAP.

person.[28] Id. at *7.

V. PETITIONERS' MOTION TO COMPEL ACCESS TO THE VACCINE SAFETY DATALINK

After careful consideration and for the reasons discussed more fully below, the undersigned denies petitioners' motion to compel access to the Vaccine Safety Datalink and denies petitioners' motion for authority to issue subpoenas to the ten named third-party managed care organizations. The undersigned is not persuaded that the discovery petitioners seek is either necessary to the resolution of the fact issues, or reasonable when balanced against the burden of production to be imposed on respondent and the third-party managed care organizations. Because petitioners' discovery request is denied, petitioners' motion for authorization of interim expert expenses is deemed moot.

A. Necessary

1. Petitioners Seek Production of Irrelevant Material

Dr. Deisher proposes to examine the rate of autism incidence in two separate groups of children: those who received the varicella vaccine, and those who did not. She explains:

> [w]e propose a retrospective epidemiological analysis of the US Vaccine Safety Datalink (VSD) between 1994 and 2005 to determine the relationship between Varicella vaccination, general health status of the child at the time of Varicella vaccination and subsequent diagnosis with autism spectrum disorder. . . . [S]hould residual human fetal DNA in vaccinations be related to subsequent regressive autism disorder, the numbers of children contained in the US VSD and the gradual uptake of Varicella should be sufficient to reveal a difference between autism spectrum disorders in Varicella vaccinated and non-vaccinated children during these years.

Deisher's MTC Decl. ¶ 10.

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[28] As noted above, Vaccine Rule 7 states that the "procedures" of RCFC 26-37 and RCFC 45 are applicable to Vaccine Act discovery determinations. Thus, when applying the "reasonable and necessary" standard in Vaccine Act discovery disputes, a special master may look for guidance in the Court of Federal Claims case law that interprets those rules of the RCFC.

Despite the stated limits of her study, petitioners' request for production from respondent and the MCOs lacks correlative limits for patient age and injury. Instead:

> petitioners seek authority to issue subpoenae to compel [respondent and the MCOs] to grant the petitioners **full and unrestricted access to all data collected by the respondent within the VSD related to the administration of vaccines, and the occurrence of neurodevelopment and other disorders from the inception of the VSD to date**.

Pet'rs' MTC 4 (emphasis added).

Petitioners did not limit their request to children born in the years Dr. Deisher seeks to study. Nor did petitioners limit their request for data to the injury of autism disorder. Petitioners' request for information about **"**other disorders" extends beyond the scope of the study Dr. Deisher has described.

This request is not the first from a petitioner in a Vaccine Program matter seeking an order to compel discovery for VSD Project data that is not relevant to the issues pending before the special master. As this court previously stated, data that is not relevant to the factual issues in the matter in which discovery is sought cannot be necessary for the special master to issue a fair and well-informed ruling. OAP, 2007 WL 1983780, at *8. That petitioners here failed to limit their request to relevant data remains a "strong reason to conclude that the proposed study is not 'necessary' to our resolution of those OAP causation issues." Id. at *8.

Dr. Deisher's intent in seeking access to the VSD Project data appears to be to obtain sufficient access to the underlying information to conduct a limitless inquiry into any vaccine and any factor that could cause autism disorder. As Dr. Deisher has said, she believes the VSD "**would allow us to determine if any other medical factors were involved in the development of autism other than the vaccines and if so what**. . . . **Indeed, the VSD was designed to do precisely what we are asking access to make it do, to determine in fact if these vaccines are safe**." Deisher's state-level varicella study ¶ 15 (emphasis added).

Petitioners fully support Dr. Deisher's attempt to conduct a broad study, stating that "[w]ide access [to VSD data] also allows the petitioners' experts to compare vaccines manufactured using other processes with those [at] issue to see if there is a consistent difference beyond the varicella vaccine. Thus, unlimited access is necessary to produce the most reliable result." Pet'rs' Reply re MTC 8.

Conducting research to determine whether vaccines are safe and what medical factors are involved in the development of autism are worthy goals for a research scientist. Pursuit of this research, however, is well outside the scope of a claim brought

under the Vaccine Program, and it would be imprudent, unnecessary, and unreasonable to grant petitioners discovery for such a purpose.

2. The Requested Post-2000 Data Would Add Little to a Study of the Varicella Vaccine

Dr. Deisher seeks VSD Project data from 1994 to 2005, a total time period of 12 years. Deisher's MTC Decl. ¶ 10. In her recent state-level varicella study, Dr. Deisher reviewed data for birth years 1992 to 1998. Deisher's state-level varicella study ¶ 6. Dr. Deisher did not specify the number of calendar years of data she examined for each patient birth year. But, it appears that Dr. Deisher used eight years of calendar data per birth year. See Id. ¶ 8 (pp. 6, 11) ("U.S. 8yr old AD vs Varicella 1992-1998," and "Correlation between Varicella Coverage and Autism Diagnosis by 8 years of age for birth years 1992 through 1998").

Because Dr. Deisher proposes to investigate the incidence of autism disorder, and because she has stated that a child is usually diagnosed with autism disorder by age three, Deisher's expert report ¶ 9, it is unclear why Dr. Deisher needs patient data through age eight, rather than age three. Dr. Deisher offered no explanation as to why she seeks the additional five years of data.

Dr. Deisher states that she is now "seeking an explanation for the continued rise in the diagnosis [of autism disorder] after the uptake of varicella leveled off," in 1998. Deisher's state-level varicella study ¶ 9. She posits that the continued increase in the rate of diagnosis of autism disorder after birth year 1998 is due to one or more sociologic factors that affect the manner in which autism is diagnosed, and not to an actual increase in the actual incidence of autism disorder. Id. ¶¶ 9, 11. In her view, it would "take some doing to unravel the sociological factors state by state and see if the special education money, internet use, etc., correlate to autism disorder prevalence from 1998 on." Id. ¶ 9.

Vaccine coverage levels reported by the CDC show that the bulk of the uptake rate in varicella vaccine occurred between calendar years 1996 to 2000, increasing from 16.0 percent to 67.8 percent, as depicted below. Pet'rs' Ex. 35. If, as Dr. Deisher posits, the difference in the rate of autism disorder among those who were vaccinated with the varicella vaccine and those who were not is a "significant difference," Deisher's MTC Decl. ¶ 11, it would be expected that such difference would be apparent in the data available from the introduction of the varicella vaccine in 1995 through calendar year 2000.

Varicella Vaccine	
Year	**CDC reported coverage** (Pet'rs' Ex. 35)
1995	unreported
1996	16.0 %
1997	25.9 %
1998	43.2 %
1999	57.5 %
2000	67.8 %
2001	76.3 %
2002	80.6 %
2003	84.8 %
2004	87.5 %
2005	87.9 %

Access to VSD Project data through 2005 may allow Dr. Deisher to test her hypothesis about the reason for the continued increase in autism disorders from birth year 1998 onward. But this work would neither prove nor disprove petitioners' theory that the MMR vaccine caused their son's autism spectrum disorder, so the requested information would not assist the undersigned in making a fair and well-informed decision on the facts of this case. Thus, it is unnecessary.

3. Assumptions and Inconsistencies in Petitioners' Theory

A review of Dr. Deisher's past and proposed work (on which she relies to support petitioners' theory of causation) reveals certain assumptions and inconsistencies in her work that militate against a finding that further work using the VSD Project data is necessary.

a. Assumption that if Varicella Vaccine Is a Trigger, then Human DNA in the Vaccine Is the Trigger

Dr. Deisher provided results from the state-level varicella study she has conducted. Pet'rs' Exs. 61. Based on this study, she asserts that a correlation exists between the rate of varicella vaccine coverage and autism disorders. She then uses this correlation as evidence to support her theory that human DNA debris in vaccines is a trigger for autism disorder. Dr. Deisher's unstated assumption is that the correlation she has detected between administered varicella vaccines and diagnoses of autism disorder unquestionably result from the human DNA debris in the manufactured vaccine only, and cannot be due to another component of the vaccine or to non-vaccine related factor.

Dr. Deisher asserts in her expert report, that biological agents—such as vaccines—may present environmental risks that can cause injury. Deisher's expert report ¶ 13. In making this assertion, Dr. Deisher relies on the Food and Drug Administration's definition of biological products. That definition includes: "a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins." Resources for You (Biologics), FDA, http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/default.htm (last updated May 11, 2010).

As is clear from the FDA's definition, biological agents include many products other than vaccines. If Dr. Deisher believes biological agents are potential environmental triggers for autism disorders, it is unclear why she concludes that it is the human DNA in certain vaccines—only—that may act as a trigger.

b. Assumption that Human DNA Must Be the Trigger, as Certain Other Possible Autism Disorder Triggers Have Been Disproved

Dr. Deisher's theory that the manufacturing method is responsible for each autism disorder changepoint is based—in part—on her elimination of several sociologic factors (identified in the scientific literature) as alternate explanations for the increase in autism disorder. She summarily asserts that because her changepoint study "has eliminated all other causes currently used to challenge vaccine causation," it is more likely than not that the "manufacture of vaccines caused a significant increase" in autism disorder. Deisher's expert report ¶ 28.

Dr. Deisher assumes that the universe of possible triggering factors is limited either: (1) to the sociologic factors mentioned in the EPA study she cites, Pet'rs' Ex. 27, to which none of the autism disorder changepoints she has identified correlate; or (2) to the DNA debris associated with human cell lines. Basically, she reasons, if it is not the first factor, it must be the second one. The universe of possible triggering factors, however, is not as limited as Dr. Deisher suggests.

The referenced EPA study identifies as possible environmental triggers a number of agents, including: intrauterine rubella, thalidomide,[29] valproate,[30] and certain metals

[29] Thalidomide - a sedative and hypnotic commonly used in Europe in the late 1950's and 1960's. Its use was discontinued because it was discovered to cause serious congenital anomalies in the fetus, notably amelia and phocomelia, when taken by a woman during early pregnancy. It is currently used in the treatment of erythema nodosum leprosum. Dorland's Illustrated Medical Dictionary 1907 (32nd ed. 2012).

(that is, mercury, cadmium, nickel) and particular chemicals (trichloroethylene and vinyl chloride) in the ambient air around birth sites. Id. at 2112. The EPA study also makes mention of the CHARGE[31] (Childhood Autism Risks from Genetics and the Environment) study that continues to evaluate other possible environmental factors. Id. at 2112.

Dr. Deisher cites to a report prepared by the Department of Health and Human Services (referenced hereinafter as the HHS report). Deisher's expert report ¶¶ 5, 8, 13. In that report, the authors state that "[r]ecent studies suggest that factors such as parental age and exposure to infections, toxins, and other biological agents may confer environmental risk." Pet'rs' Ex. 17 at 27 (HHS report). The authors further state that "[p]rogress in identifying environmental factors that increase autism risk has been made recently," citing to six different published articles.[32] Id. at 26.

The HHS report contains an extensive discussion about the various environmental factors under consideration as possible risk factors for autism and reviews the recently published works examining such factors. Id. at 25-36. Because Dr. Deisher is clearly familiar with this report—which was filed by petitioner and discussed directly by Dr. Deisher—it is puzzling to the undersigned why she has taken the position that her

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[30] Valproate - a simple eight carbon branched-chain fatty acid used as an anticonvulsant in the treatment of epileptic seizures, particularly absence seizures; administered orally. Dorland's Illustrated Medical Dictionary 2020 (32nd ed. 2012).

[31] CHARGE was established in 2003 by the University of California-Davis Center for Children's Environmental Health and Disease Prevention, and is supported by both government and private funding. http://beincharge.ucdavis.edu/newsupdates.php.

[32] B. Eskenazi et al., Organophosphate Pesticide Exposure and Neurodevelopment in Young Mexican-American Children, 115 Environ. Health Perspect. 792-98 (2007); R.F. Palmer et al., Environmental Mercury Release, Special Education Rates, and Autism Disorder: An Ecological Study of Texas, Health Place, 12 Health Place 203-09 (2006); R.F. Palmer et al., Proximity to Point Sources of Environmental Mercury Release as a Predictor of Autism Prevalence, Health Place, 15 Health Place 18-24 (2009); V.A. Rauh et al., Impact of Prenatal Chlorpyrifos Exposure on Neurodevelopment in the First Three Years of Life Among Inner-City Children, 118 Pediatrics 1845-59 (2006); E.M. Roberts et al., Maternal Residence Near Agricultural Pesticide Applications and Autism Spectrum Disorders Among Children in the California Central Valley, 115 Environ. Health Perspect. 1482-89 (2007); G.C. Windham et al., Autism Spectrum Disorders in Relation to Distribution of Hazardous Air Pollutants in the San Francisco Bay Area, 114 Environ. Health Perspect. 1438-44 (2006).

changepoint study has "eliminated all other causes currently used to challenge vaccine causation." Deisher's expert report ¶ 28.

c. Assumption that if Human DNA in the Varicella Vaccine Is a Trigger, then Human DNA in the MMR Vaccine Is a Trigger

Dr. Deisher appears to make the unsupported assumption that if the DNA present in the varicella vaccine manufacturing process is shown to be a trigger for autism disorder, this finding would be sufficient to establish that the DNA present in the MMR vaccine manufacturing process similarly operates as a trigger for autism disorder.

According to Dr. Deisher, the amount of human fetal DNA contained in a single dose of the varicella vaccine is 2 micrograms. Deisher's MTC Decl. ¶ 10. To illustrate how much DNA is present in the varicella vaccine, she notes, by comparison, that the amount of DNA in the rubella component of a single dose of the MMRII vaccine is only 200 nanograms. Id. ¶ 10. Because 1 microgram is equivalent to 1000 nanograms, Dr. Deisher's comparison points out that the varicella vaccine contains 10 times the amount of human fetal DNA than does the MMR vaccine.

Implicit in Dr. Deisher's discussion regarding the proposed study is a belief that the larger amount of DNA in the varicella vaccine (relative to the MMR vaccine) could be an important factor if the varicella vaccine is shown to be a trigger for autism disorder. Dr. Deisher explained that she prefers to study the varicella vaccine, and not the MMR vaccine at issue in this matter, because it has had a slow uptake rate and its content is "dirty" (as established by its sizeable DNA content). Pet'rs' MTC 2, 16 ("varicella is the 'dirtiest' of the vaccinations"). See also Pet'rs' Reply re MTC 22; Deisher's MTC Decl. ¶ 10.

Because—as Dr. Deisher recognizes—the amount of DNA in a vaccine may play a role in causing injury, a finding—if any—that DNA content in the varicella vaccine is a causal trigger for autism disorders may not support a finding that vestigal DNA in the MMR vaccine is a similar trigger. Because the MMR vaccine is at issue in this matter, a finding regarding the varicella vaccine with questionable applicability to the MMR vaccine can hardly be deemed necessary to the resolution of this case.

d. Inconsistency as to Whether Thimerosal Was a Trigger for the 1988 Changepoint

Dr. Deisher takes inconsistent positions in her changepoint study and her state-level varicella study regarding the role of thimerosal as a possible trigger for autism disorders. In her October 2012 state-level varicella study, Dr. Deisher takes the position that thimerosal and the MMR vaccine are both responsible for the 1988 changepoint,

Deisher's state-level varicella study ¶ 11, while in her March 2011 changepoint study, Dr. Deisher vigorously disputes any possibility that thimerosal was responsible for the 1988 changepoint, Deisher's changepoint study 15-16.

In her March 2011 changepoint study, Dr. Deisher reports that a thimerosal-containing vaccine was added to the CDC recommended vaccine schedule on three occasions. Id. 13-14. One of these added vaccines was the Hib vaccine, and according to Dr. Deisher, its addition roughly corresponds to one of the three observed changepoints in autism disorder incidence. Id. 13. The single dose Hib vaccine was added to the CDC's recommended vaccination schedule in mid-1989, an addition that Dr. Deisher claims would have increased the total amount of thimerosal a fully-vaccinated child would receive. Id. 13. But Dr. Deisher discounts the possibility that the Hib vaccine was responsible for the 1988 changepoint. She states that the coverage level for this vaccine was initially low (29%), and notes that no change in the administration of other thimerosal-containing vaccines can be matched with the other two autism disorder changepoints she identified, 1981 and 1995. Id. 15-16 (citing Pet'rs' Ex. 35). Moreover, Dr. Deisher acknowledges that although thimerosal levels in childhood vaccines have been reduced over the last decade (roughly since the year 2000), rates of autism disorder have continued to increase. Id. 16.

Yet, 19 months later, in her October 2012 state-level varicella study, Dr. Deisher attributes the increase in autism disorder from birth year 1980 through 1992 to the MMR II vaccine and an "increased Thimerosal load in vaccines." Deisher's state-level varicella study ¶ 11. But she offers no explanation for the shift in her position between March 2011 and October 2012 concerning the causal role of thimerosal. Nor does Dr. Deisher provide any specifics about which vaccines she believes are contributing to the increased Thimerosal load.

Dr. Deisher's opinion in support of petitioners' theory relies, in part, on her theory that the changepoints she observed at 1981 and 1988 were related solely to the MMR vaccine at issue in this matter. Absent from her expert report was any mention of thimerosal. Nor have petitioners in this case relied on a theory that thimerosal caused their son's autism spectrum disorder.

e. Inconsistency Regarding Whether All Vaccines Manufactured with Human Fetal Cells Are a Trigger

Dr. Deisher lists nine vaccines that are produced by a manufacturing method that involves the use of human fetal stem cells. Deisher's expert report ¶ 17. Of the listed vaccines, only varicella, Hepatitis A and MMR II were on the market during the time period covered by her study, that is, from 1970 to 2002. Id. Of the three available vaccines, Dr. Deisher links only two, the varicella and MMR II vaccines, to the three identified changepoints in the rate of autism disorder.

According to Dr. Deisher, the viruses for the varicella and Hepatitis A vaccines are both manufactured using a cell line known as MRC5, Id. (citing Pet'rs Exs. 28 & 29), and the rubella virus in the MMR II vaccine is manufactured using a cell line known as WI-38, Id. (citing Pet'rs Ex. 30). Both cell lines are derived from a normal fetus. Id. (citing Pet'rs Exs. 31 & 32).

Curiously, despite the assertion that the Hepatitis A vaccine is manufactured in the same manner as the varicella and MMR II vaccines, and despite the fact that the varicella and Hepatitis A vaccines are manufactured with the same cell line, Dr. Deisher makes no allegation that the Hepatitis A vaccine is linked to autism disorder.

The undersigned appreciates Dr. Deisher's theory to be that DNA debris left by the vaccine manufacturing process serves to trigger autism disorder. Consistent with this theory, every vaccine manufactured in this method might be expected to operate as a possible trigger. But Dr. Deisher does not assert this. Nor does she offer an explanation for her inconsistent position regarding which vaccines are a trigger for autism disorder. Dr. Deisher also fails to offer insight into what additional factors might determine whether a vaccine acts as a trigger.

4. Conclusion

Petitioners have failed to carry their burden to show that the discovery they seek is necessary to the resolution of this matter, and at least some of the discovery they seek is plainly irrelevant. Even if a study of the varicella vaccine could be construed to be necessary, such a study could be completed with data through calendar year 2000; the additional data petitioners seek through 2005 would be unnecessary. But, most significantly, the numerous unsupported assumptions and inconsistencies in Dr. Deisher's theory make it very difficult to find that any additional discovery is necessary at this time.

B. Reasonable

For the sake of completeness, the undersigned considers whether petitioners' discovery request is reasonable. As discussed in fuller detail below, granting petitioners' motion would be the equivalent of ordering the respondent and the MCOs to conduct an original study to support petitioners' vaccine claim. This undertaking would impose an unreasonable burden on respondent and the third-party MCOs. Such grant of petitioners' discovery request also would disrupt the contractual agreement between the CDC and the MCOs that carefully defines the rights each MCO has retained to grant or deny any outside researcher access to its data. The interference with these well-defined contractual rights is not justified in this case, because petitioners have failed to establish that the study Dr. Dieisher proposes to conduct would inform the relevant issues brought by petitioners.

1. Effectively Ordering the Requested Discovery Would Constitute an Order to Conduct a Study

Petitioners assert that Dr. Deisher merely seeks access to the data, and does not seek the participation of either respondent or the MCOs in her work. Pet'rs' Reply re MTC 1, 12 ("Petitioner merely seeks access to the data in the form in which it is maintained by the VSD."). Similarly, in 2007, petitioners in the OAP argued that their request to access VSD Project data was not a request for respondent to undertake a study. OAP, 2007 WL 1983780, at *8.

Evaluating the presented discovery request in 2007, the special masters assigned to hear the OAP cases (including the undersigned) recognized and addressed the difficulty with ordering either the CDC or the MCOs to shift time, resources and effort from the work on which each is currently focused to accommodate a proposed study by any Vaccine Program petitioner:

> Medical scientists employed by the CDC and the MCOs are the ones who make the judgment as to how to use their resources, weighing the utility of one possible use against other potential uses. The PSC now asks us to, in effect, take over that function, of deciding how the resources of the CDC and the MCOs should be used. But we have no idea about the other potential uses, and, thus, are in no position to take over that weighing function. We do not find it reasonable that we do so.

Id.

A review of the effort that would be required from the respondent and the MCOs to provide Dr. Deisher with access, as well as the consequences to the respondent for failing to participate in Dr. Deisher's study, indicates that now, as in 2007, an order to compel access to data--as requested by petitioners--effectively would constitute an order to conduct a study.

a. The Results of the Proposed Study Could Impact Other Vaccine Program Claims

As petitioners point out, other petitioners bringing Vaccine Program claims have asserted the same causation theory that petitioners here are advancing. Pet'rs' Reply re MTC 23-24. This theory contemplates that the vaccine manufacturing method using human fetal stem cells has allowed a deposit of DNA debris in vaccines that triggers the onset of an autism spectrum disorder. In other cases, petitioners are awaiting the outcome of this case because they are alleging a similar theory.

The undersigned also appreciates that were she to compel respondent to grant petitioners' expert access to the Data Sharing Program, respondent would very likely involve CDC researchers in Dr. Deisher's study effort. Moreover, Dr. Deisher's study results are unlikely to receive peer review prior to petitioners filing a further expert opinion in this matter, respondent's participation in the study effort would afford the Secretary her only opportunity to understand how Dr. Deisher conducted her work.

Because petitioners have filed into this case the preliminary results of the state-level study Dr. Deisher previously filed in another Vaccine Program claim, Pet'rs' Ex. 61, the undersigned would expect Dr. Deisher' work in this claim to be used in other pending vaccine claims as well. The impact of this proposed study on other Program cases is without question.

b. Data in the Possession of the CDC

The procedures that CDC follows to accommodate an outside researcher granted access to data contained in the Data Sharing Program were set forth in a publicly available document filed into the OAP proceedings.[33] During the OAP proceedings, the Petitioners' Steering Committee (PSC)[34] sought and ultimately received--for two of their experts--access to the final set of data for one published study.[35] April 14, 2005 Discovery Order 1. Detailed procedures pertaining to data access, data confidentiality, and restricted use of the data were set forth in a Discovery Order; the procedures developed by the CDC reflect the Center's efforts to carefully monitor the access of outside researchers' to the data stored within the Center. As prescribed by the Discovery Order, an outside researcher who is afforded access to the CDC's facility in Maryland is assigned a technical monitor who remains on-site at all times during the expert's use of the dataset. Id. Section II ¶¶ 1, 4.

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[33] The OAP proceedings are available on the website of the U.S. Court of Federal Claims, http://www.uscfc.uscourts.gov/node/2718.

[34] The PSC was formed by a number of petitioners' counsel in the autism cases who combined efforts to conduct discovery and to otherwise represent the interests of the autism petitioners in the Omnibus Autism Proceeding. OAP, 2007 WL 1983780, at *2.

[35] The protocol defined in the Discovery Order was established by the parties' agreement. The Special Master approved the proposed Discovery Order without modification. OAP, 2007 WL 1983780, at *3; Discovery Order 7.

As described in the Discovery Order:

> The technical monitor will perform a disclosure review of the "output." "Output" for the purposes of this Discovery Order, is defined as any and all documents generated by the petitioners' experts while they are present at the CDC's RDC at NCHS,[36] including all computer-generated documents and personal notes. The only output petitioners' expert may remove from the RDC are summary tables that provide no means for the identification of individual patients or individual MCOs. (Any summary table that includes one or more cells with counts less than five is considered identifiable information and therefore will be restricted from leaving the RDC.) None of the petitioners' experts will be allowed to take with him or her any output not deemed by the technical monitor to meet this criteria. The technical monitor will destroy this rejected output without further disclosure to any other individual, including but not limited to any employees, agents, or other representatives of respondent.

Id. Section II ¶ 4(b). As provided by the Discovery Order, access to data stored at the CDC is closely monitored.

c. Post-2000 Data Is in the Possession of the MCOs

Because each MCO is in sole possession of the data it has collected after the year 2000, the individual MCO bears the entire burden of providing Dr. Deisher with access to the requested data. Respondent has no role in providing petitioners with access to any post-2000 data. The MCOs have described in detail the work each managed care entity would have to undertake separately to provide post-2000 data to Dr. Deisher. See MCOs' Obj. to MTC 20-21.

> First, participating MCOs would need to spend weeks, if not months, working in partnership with Petitioner's retained expert, Dr. Deisher, to formulate protocols appropriate to the MCO's data and the proposed Study Plan. This would include detailed discussions relating to each of the ICD-9 codes identified in the Study Plan and each MCO's specific policies regarding those codes. See [Deisher's MTC Decl.] ¶ 13. This would presumably result in a refined list of variables to be evaluated. Then, in conjunction with Dr. Deisher and her staff, MCO researchers would need to formulate appropriate comparison groups of patients to study against the individuals of interest to Petitioners. Because of their familiarity with their own files, most of this work could not be "outsourced," nor done by Petitioners. It would be left to the MCOs.

[36] Research Data Center at the National Center for Health Statistics.

> This refinement process would be followed by weeks during which the MCOs' statistical analysis and programmers would need to create SAS computer programs containing numerous algorithms sufficient to filter the VSD raw data and generate the necessary datasets for the study. Since the MCOs do not currently have available statistical analysts and programmers sufficient to create these programs, each MCO would presumably need to hire, and train, programmers to carry out this formidable task. Once created, the SAS computer programs would then need to be run in various MCO databases. Another layer of complexity and additional work to be imposed upon the MCOs is ensuring that these data sets are compatible with pooling of the analysis across MCOs.
>
> After each MCO generated a relevant dataset, the underlying data would then need to be chart-verified in order to ensure a scientifically sound analysis. In fact petitioners' Study Plan includes specific requests that inherently require chart-review. The Study Plan states, for instance, that "filters . . . that will be used include: continuous enrollment for 5 years, birth weight higher than 2500g, lack of severe perinatal or congenital disorders [and] [a]bsence of previous blood transfusions or exposure of other sources of non-host human DNA." See [Deisher's MTC Decl.] ¶ 13. They also seek patient-specific information "as to the type, date, brand and identifying numbers of each vaccine administered, the location of the vaccination site on the body, the medical and genetic background of the child and an analysis of all subsequent events." Motion at 10. For certain MCOs, this information is not routinely contained in the compiled VSD data. In such instances, a review of each individual patient's medical records would be necessary, a task consuming additional MCO staff resources.

MCOs' Obj. to MTC 20-21. The effort required by each MCO to respond to petitioners' discovery requests for data after the year 2000 would be significant.

d. Conclusion

Notwithstanding petitioners' insistence that they are not requesting that either respondent or the MCOs conduct the study they have proposed, a grant of petitioners' discovery request would invoke access protocols that effectively would require respondent and the MCOs to conduct the original study proposed by Dr. Deisher. Such a requirement would impose an undue burden on the ability of each entity to determine how to allocate its own time and resources.

The standard for the "reasonable" inquiry is whether the burden on each MCO as balanced against the special master's need for the evidence, is reasonable. Because Dr. Deisher could complete the proposed study with pre-2000 data, the reasonableness of issuing an order imposing burdens on the MCOs--as petitioners' request requires--is dubious.

2. Ordering Discovery Would Interfere with Established Contractual Agreements

As discussed during the OAP in 2007, any order compelling respondent to provide Dr. Deisher with access to the Data Sharing Program data risks undue interference with the contractual agreements between the CDC and the MCOs. OAP, 2007 WL 1983780, at *12. Under those agreements, the MCOs retain the right to deny access to any of the data sets sent to the CDC between 1990 and 2000, as well as to deny access to the post-2000 data in the possession of the individual MCOs. MCOs' Ex. D at 17-18. But, the issuance of an order to compel would abridge an MCOs' access rights.

a. Data Sharing Program Data in the Possession of the CDC

All proposed studies using Data Sharing Program data must be approved by both the CDC and by each MCO whose patient data will be used in the study. Resp't's Resp. to MTC 21; MCOs' Ex. D at 17.

The published CDC procedures for accessing data through its Research Data Center (RDC), including the VSD Project data, describe in detail the procedures for obtaining access to Data Sharing Program data. Among the prescribed procedures for access to the data is presenting a request for approval to both the CDC and the MCOs. See MCOs' Ex. D at 17-22.

The CDC evaluates proposals for data through the VSD Data Sharing Program based on the following criteria. The first of the listed criteria has primacy in the evaluation:

- Scientific and technical feasibility of the project.
- Availability of resources at RDC.
- Risk of disclosure of restricted information.

Id. at 20.

If the CDC determines that the proposal satisfies these evaluation criteria, the proposal is then reviewed by the appropriate MCO IRBs. Id. at 20. The CDC explains that the various IRBs may require the outside researcher to provide a

more detailed description of the study, may differ from one another in their response times or their evaluation criteria, and may have unique policies regarding access to data.[37] Id. Despite their mutual collaboration in the Vaccine Safety Datalink project, differences persist among the MCOs because each MCO remains a separate private entity and retains the freedom to act accordingly. Id.

The CDC takes care to inform outside researchers who are seeking access to Data Sharing Program data that "the MCOs have broad decision-making authority over data release as well as a recognized need and right to protect proprietary data." Id. at 17. The CDC explicitly states that it "is not involved in the MCO IRB process at any time." Id. at 21. This protocol is notably different after the year 2000 because CDC has no access to that data.

b. Post-2000 Data in the Possession of the MCOs

For data after the year 2000, executed contracts set forth the agreement between the government and the MCOs with respect to the data access that the MCOs will provide to those outside the organization:

> The [MCO] is creating and maintaining these automated databases to provide the Government the ability to carry out scientifically rigorous studies of specific hypotheses related to the safety of publicly available vaccines.
>
> (1) The [MCO] shall provide the Government with a mechanism by which the Government and other health plans participating in the VSD project can plan and conduct epidemiologic studies in a timely manner. . . .

MCOs' Ex. A, attach. A at 7.

Outside researchers, like Dr. Deisher, may gain access to post-2000 VSD data, by seeking the approval for such access from each MCO whose data the researcher seeks.

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[37] The CDC has advised that "[i]n compliance with federal law and regulations, access by external researchers to a portion of the VSD data files or to datasets from VSD published studies requires review and approval by the appropriate IRBs of the relevant MCOs." MCOs' Ex. D at 20. But no citation is provided, and neither the respondent or the MCOs mentioned any such law or regulation in their briefs. A citation to the applicable law or regulation would be welcome.

> Data from the VSD project collected after December 31, 2000 are not available through the RDC VSD Data Sharing Program. VSD data beyond 2001 can be accessed through a formal collaboration with an MCO and the external researcher must work through MCO procedures. It should be noted that collaboration is at the discretion of the MCO. Such collaboration would be outside the scope of the VSD Data Sharing Program and, therefore, data would not be accessed at the RDC. CDC cannot guarantee external investigators' ability to gain access to the VSD data at the MCOs.

MCOs' Ex. D at 18.

c. Conclusion

A private MCO enters into a contractual relationship with the CDC to provide its data for use in the VSD Project, rightfully expecting that the terms of the contract will set the limits of what it will be asked to do and will define its rights with regard to its patient data, the property of interest. It is no small matter for a court to override such private contracts by judicial order.

As noted during the OAP in 2007, issuing an order that interferes with the contract arrangements made between the CDC and the MCOs to provide Dr. Deisher with access to the data she seeks is patently unreasonable before she attempts to gain access to the data through the established procedures. OAP, 2007 WL 1983780, at *12. As discussed in more detail later in this Order, petitioners acknowledge that Dr. Deisher has not followed the CDC's usual Data Sharing application process and that she has no intention of doing so.

3. Dr. Deisher

a. The Usefulness of the Discovery Petitioners Seek is Dependent Upon the Analysis Applied by Their Expert

Unlike a standard request for production of documents, the discovery petitioners seek is raw data and thus is not information that could be provided to this court in the manner in which it is received by petitioners from respondent. The data will require the analysis of petitioners' expert, Dr. Deisher. Without this analysis, an order directing respondent or the MCOs to provide petitioners with access to any data would be meaningless, and the efforts by respondent and the MCOs to comply with that order would be misspent.

The importance of Dr. Deisher's role in this case requires that the undersigned give consideration to Dr. Deisher's ability to successfully lead a research study. Granting

petitioners access to raw data without an expectation that Dr. Deisher could successfully complete her proposed study would defeat the purpose of the discovery request.

For the proposed study, Dr. Deisher plans to serve as the principal investigator, who leads a research team comprised of a statistician, a computer programmer, and a computational analyst. Pet'rs' Ex. 47. Petitioners point to Dr. Deisher's curriculum vitae to "show[] her credentials," and to furnish support for their assertion "that a team led by her [could] perform [the proposed study] competently." Pet'rs' MTC 3-4.

Dr. Deisher's CV shows that from 1988 to October 2007, she was employed by six different commercial biotechnology companies in increasingly responsible research positions. Deisher's CV at 2-3. During this period of time, Dr. Deisher appears as one of several named co-authors on more than 20 published articles. Id. at 4-5. A review of the articles indicates that many are related to cardiac research; none are related to autism disorder research. Id. at 4-5. After late 2007, Dr. Deisher is a named co-author on one article published in a scientific journal, the topic of which is related to cardiac research. Id. at 4. Dr. Deisher's role in conducting the various studies on which the articles were based cannot be discerned from the filings before the undersigned.

Dr. Deisher's CV lists one completed study since 2008. That study is her changepoint study. Id. at 4. The study remains unpublished despite Dr. Deisher's efforts to get it published in Autism Research.[38] Dr. Deisher attributes the rejection of this study by the journal to the "controversial" nature of the study, Deisher's expert report ¶ 29, but Dr. Deisher fails to explain why her study is deemed controversial.

Her changepoint study offers two conclusions: first, that there are three changepoints in the incidence of autism disorder over the time period spanning from 1970 to 2002, and second, that the sociologic factors of increased professional and parental awareness, revisions in the definition of autism disorder in the Diagnostic and Statistical Manual of Mental Disorders (DSM), and federal funding for special education are not responsible for any of the three observed changepoints. Deisher's changepoint study 4, 18. There is no mention in Dr. Deisher's changepoint study of her theory in this case that the residual DNA from human fetal stem cells deposited in vaccines during the

[38] Dr. Deisher notes that this work was funded by the MJ Murdock Charitable Trust, Pet'rs' Ex. 26 at 18, which according to information on Deisher's CV, provided her with a $500,000 grant to study "Population, Bioinformatics and In Vitro Studies into the Relationship between Residual Human DNA Vaccine Contaminants and Autism." Deisher's CV at 3. Dr. Deisher's inability to produce a paper of publishable quality, after receiving a substantial grant, does not lend support to petitioners' claim that she is capable of competently leading a study.

vaccine manufacturing process is the environmental agent responsible for the three changepoints in the incidence of autism disorder.

The conclusions reached in Dr. Deisher's changepoint study build on work previously published by other researchers, and cited by Dr. Deisher in her expert report. Deisher's MTC Decl. ¶ 7. One of the earlier works on which Dr. Deisher's changepoint study rests is a study published in 2010 by two researchers from the U.S. Environmental Protection Agency (EPA).[39] In that article, the researchers identify as a changepoint in the incidence of autism disorder the year 1988. Pet'rs' Ex. 27 at 2113. That changepoint coincides with one of Dr. Deisher's three identified changepoints. Deisher's changepoint study 1; Deisher's expert report ¶ 12. Dr. Deisher reports that because she used the more sophisticated data analysis method of segmented line fit algorithms than did the EPA researchers (who applied a "hockey stick" method of analysis[40]), she was able to identify two additional changepoints. Deisher's expert report ¶¶ 9-12.

The EPA authors discussed in their study an article suggesting that wider awareness of autism, greater motivation of parents to seek services, and increased funding for services might serve as factors contributing to the increase in autism disorder diagnosis. Pet'rs' Ex. 27[41] at 2114-15. But, the EPA authors cautioned that because the sociologic factors could neither be documented nor quantified, the theory pertaining to the impact of sociologic factors could not be tested. Id. at 2115.

Nonetheless, Dr. Deisher attempted to build on this work by devising a method to determine whether the three changepoints she had identified could be associated with the mentioned sociologic factors. Deisher's changepoint study 4-13. She found no correlation and concluded that none of the posited sociologic factors was responsible for any of the changepoints she had detected in the incidence of autism disorder. Id. 4, 18.

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[39] M.E. McDonald & J.F. Paul, Timing of Increased Autistic Disorder Cumulative Incidence, 44 Envtl. Sci. & Tech. 2112 (2010) (both authors were employed by the National Health and Environmental Effects Research Laboratory, U.S. Environmental Protection Agency).

[40] Dr. Deisher described a hockey-stick algorithm as one that "fits 2 lines connected at the changepoint by a quadratic curve; the reported fit parameters using this model are 1) the y-intercept, 2) the slope of the pre-changepoint line, 3) the change in slope, and 4) the changepoint year." Deisher's changepoint study at 8. Practically speaking, this is a line chart with a single sharp increase at a changepoint year. The line connecting the data points resembles a hockey stick, with the "blade" formed from data points up to the changepoint year, and the "shaft" formed from data points after the changepoint year.

[41] I. Hertz-Picciotto & L. Delwiche, The Rise in Autism and the Role of Age at Diagnosis, 20 Epidemiology 84 (2009).

Dr. Deisher's work addresses the same issues that were addressed in the two earlier published studies, neither of which was deemed too controversial for publication. It is thus unclear to the undersigned why Dr. Deisher insists that her work was too controversial to receive publication.

Dr. Deisher avers that she can no longer professionally collaborate with the "illustrious companies" in the field of commercial biotechnology for which she formerly worked. Deisher's CV at 1. Thus, the question of whether Dr. Deisher can lead a team to competently perform the proposed study, with limited support for her research efforts, must be considered.

There is ample evidence in the record that Dr. Deisher's peers, who have reviewed the VSD study she proposes and her qualifications to conduct the study, have found both the proposed study and her qualifications to be wanting.

Dr. Deisher relates that she applied, unsuccessfully, for NIH funding to finance her proposed VSD study. Deisher's expert report ¶ 29. As evidence that her efforts were unavailing, petitioners have furnished a copy of the NIH rejection notice. Pet'rs' Ex. 62. That notice contains unvarnished critiques of Dr. Deisher's application by 3 NIH reviewers. Id. at 2-8. Although the 3 reviewers were not named, NIH provided a list of its 29 reviewers, which included the 3 individuals who reviewed Dr. Deisher's application. Id. at 9-10.

Each of the reviewers NIH has retained is well-credentialed, holding either a doctorate or a medical degree. Id. Most are university professors, but a few serve as research scientists in government or industry. Id. To the extent that Dr. Deisher presents herself as a research scientist capable of conducting epidemiologic research, these reviewers are her peers.

According to petitioners, "[t]he grounds for [the NIH] rejection" were Dr. Deisher's lack of experience "as a peer[-]reviewed researcher" and her research bias. Reply re MTS 1. A review of NIH's rejection provides another view.

The three critiques prepared by the NIH reviewers show that Dr. Deisher's peers held a very poor view of her proposed study as well as her suitability to conduct such a study. The critiques are notably devoid of "strengths," but are replete with "weaknesses." Uniformly critical, the reviewers offered the following:

(1) Evaluating the overall impact of the study:

> The proposed methods are weak . . . and there are major methodological concerns throughout that substantially reduce the impact of this study. (Critique no. 1) Pet'rs' Ex. 62 at 2.

There are several conceptual and design limitations for [the VSD study]. The approach is poorly described and does not account for inherent limitations in the available data that would be used. (Critique no. 2) Id. at 4.

Instead of showing solid published reports in the background, [Dr. Deisher] brings up anecdotal reports and personal communications to rationalize the approach. The epidemiological link that is being studied will be from a recall which is likely to be biased. Several, serious methodological issues have been identified with the proposed aims. There is little plan to explain how the data will be interpreted. (Critique no. 3) Id. at 6-7.

(2) Evaluating the significance of the study:

The concept of birth year change points is a weak approach to defining causal links between vaccine exposure and adverse outcomes. (Critique no. 1) Id. at 2.

[Dr. Deisher] has not published any evidence to support this investigation, but seek[s] to gather evidence from a submitted manuscript. (Critique no. 3) Id. at 7.

(3) Regarding the investigator [Dr. Deisher]:

[Dr. Deisher] has no clear background in the epidemiological and statistical methods required for the [proposed VSD study]. (Critique no. 1) Id. at 3.

[Dr. Deisher] is not trained as a statistician or epidemiologist and does not acknowledge the assumptions and complexities of interpreting data analyzed in the way it is proposed. (Critique no. 2) Id. at 5.

Junior members of the team may have adequate statistical programming skills, but guidance from [Dr. Deisher] is lacking for "more sophisticated programming" approaches. (Critique no. 2) Id.

[Dr. Deisher has] [n]o proven record of epidemiological research, and [n]o proven record of any relevant scientific publication on this subject. (Critique no. 3) Id. at 7.

(4) With respect to Dr. Deisher's proposed approach:

The methods are inadequately described and cannot be fully evaluated. (Critique no. 1) Id. at 3.

> Inclusion/exclusion and sampling criteria are not adequately described. It is unclear which children will be included and how autism/autistic symptoms will be classified from which databases. Although "matching" has been proposed, the comparison group definition and matching criteria are unclear. (Critique no. 2) Id. at 5.

(5) Addressing Dr. Deisher's research group:

> Sound Choice Pharmaceutical Institute does not have a clear record of any extramural, peer reviewed funded research, particularly in the field of epidemiology. (Critique no. 1) Id. at 3.
>
> There is no intellectual or institutional infrastructure to support [the VSD study] with any rigor. (Critique no. 2) Id. at 6.
>
> No prior experience; the staff do not have prior record of conducting research of this capacity; no formal design is proposed, the data collections etc lack details. (Critique no. 3) Id. at 8.

Although petitioners make assertions to the contrary, the evidentiary record before the undersigned contains a withering assessment of Dr. Deisher's ability to competently lead the proposed study. Petitioners here seek extraordinary relief, and the undersigned is reluctant to substitute her scientific judgment for that of the NIH reviewers—a panel of Dr. Deisher's peers—who have found her proposed study to be critically deficient. In the undersigned's view, the NIH reviewers' comments merit weighted consideration.

b. Ordering Respondent's Participation to Bolster Dr. Deisher's Credibility

Dr. Deisher takes the position that respondent should collaborate with her to conduct the proposed study:

> I understand that the fact that [Sound Choice Pharmaceutical Institute] is affiliated with a moral position[42] has a significant effect on the perceived credibility of our work. Therefore funding of the needed additional work should be removed from those donation sources and **the additional work I seek to undertake should be done with the collaboration of the respondent here so that any issues may be addressed**.

[42] Dr. Deisher's CV identifies AVM Biotechnology, as the "marquee prolife biotech company worldwide" and Sound Choice Pharmaceutical Institute as "providing . . . resources to encourage safe and moral medicines and therapies." Deisher's CV at 1. Dr. Deisher is the founder and head of each company. Id.

Deisher's MTC Decl. ¶ 4 (emphasis added).

Implicit in Dr. Deisher's position is the assumption that the scientific soundness of her work has been called into question because the organization she founded has adopted a particular moral position. Rather, it appears to the undersigned that the difficulty lies with Dr. Deisher's election to speak as an advocate and not to conduct research.

For the past five years, Dr. Deisher has spent much of her time as an advocate – lecturing and making public appearances across the country in support of her position regarding the use of fetal stem cells in research. Deisher's CV at 8-9. Her research has slowed, as have her scientific publications. Her last completed research study remains unpublished. Since agreeing to serve as an expert for petitioners in this case, Dr. Deisher has begun a state-level varicella vaccine study. Petitioners have filed the preliminary results of this study into the record here. See Pet'rs. Ex. 61.

Dr. Deisher's CV shows little in the way of recent research accomplishment and thus has provoked questions about her suitability to conduct the proposed study. If the choices Dr. Deisher has made about how to spend her time have affected her credibility in the scientific community as a research scientist, the consequences for those choices must rest with Dr. Deisher. Petitioners who have retained Dr. Deisher to serve as an expert in this matter are fully apprised of these factors that have diminished the "perceived credibility of [her] work." Deisher's MTC Decl. ¶ 4.

Dr. Deisher's request that respondent collaborate with her to conduct the proposed study would place a substantial burden on respondent. To the extent that Dr. Deisher has proposed a collaboration with respondent to cure her own credibility issues in the scientific community, the request cannot stand.

c. Petitioners Seek to Avoid the Usual Procedures for Requesting Access to All Vaccine Safety Project Data

Dr. Deisher acknowledges she has not requested the data she seeks through the Data Sharing Program. Pet'rs' MTC 6-7; Pet'rs' Reply re MTS 1-3. Petitioners report that neither they nor Dr. Deisher have the money necessary to conduct Dr. Deisher's proposed study, should she gain access to the VSD data through the established protocol. Petitioners argue that attempting to get access to the data without funding to do the study would be imprudent. Reply re MTS 2-3.

Petitioners characterize the process to gain access through the Data Sharing Program as "long, cumbersome[,] expensive, and…largely unsuccessful." Pet'rs' MTC 6. Petitioners assert that they "simply do[] not have the resources to follow that procedure." Id.

Petitioners seem to base their assertion that the process is "largely unsuccessful," on the experience in 2006 of a former expert in an unrelated matter. See Pet'rs' Ex. 48. The expert in that matter applied to the Data Sharing Program requesting the final data set of a published study, so that he could reanalyze the data. That expert submitted applications to eight MCOs. One MCO refused his request, and CDC refused to provide the data from the seven MCOs willing to grant him access. Id. ¶¶ 7, 14, 16.

The CDC's rules state that in the case of an outside researcher seeking a final data set of a published study, the CDC will release the data set only if each MCO whose data was included in that particular dataset consents to the disclosure. MCOs' Ex. D at 21. In contrast, the CDC's rules provide that if an outside researcher seeks data for a new vaccine safety study, as Dr. Deisher does, then the CDC will provide the data from those MCOs who have approved the request (even if others declined the request). Id. The researcher must have approval from at least two MCOs, however, because the privacy protocols prohibit the researcher from being able to identify the MCO from which any data record might have originated. Id.

Because the data Dr. Deisher seeks is unlike that sought by the expert whose 2006 experience petitioners have cited here, the 2006 experience cannot inform what Dr. Deisher's experience would be, should she present an application to the Data Sharing Program. It would appear that petitioners are not aware that the CDC treats requests differently, depending on the data requested.

The MCOs report that various researchers have accessed the VSD data successfully. Between 1990 and 2005, over 65 scientific articles have been published by researchers working with data obtained through the VSD Project. MCOs' Obj. to MTC 11 (citing Vaccine Safety Datalink (VSD) Project 2004-2005 Annual Report[43]). But the rate at which outside researchers succeed on their applications to the Data Sharing Program is unknown, because there is no information in the record regarding the number of unsuccessful applicants for VSD Project data.

d. Conclusion

Contrary to petitioners' claim, access to VSD Project data through the Data Sharing Program is possible, albeit not certain. While a researcher can ease her burden by limiting the number of MCOs to which she applies, the individual application process is neither quick nor easy. But, a ponderous application process does not merit a discovery order to circumvent the carefully established protocols for data access. Nothing in Vaccine Rule 7 or the Vaccine Act case law suggests that a special master

[43] Respondent reports that this is the most recent annual report prepared. MCOs' Obj. to MTC 7 n.1.

should issue a subpoena to spare petitioners the time, expense, and uncertainty of pursuing the information on their own.

Dr. Deisher's very ability to conduct the proposed study is doubtful. The rejection of her work by the scientific community does not seem to stem from her research "bias," as Dr. Deisher insists--but from her own lack of demonstrated scientific research.

As a policy matter, the undersigned is loathe to signal to researchers that litigation has primacy over science in determining whether access to the VSD Project data should be compelled. Such a signal could encourage researchers to affiliate themselves with a Vaccine Program claim, rather than following CDC's established procedures for gaining access to the data. Practically speaking, researchers with solid prospects of obtaining CDC and MCO approval for data access are less likely to make use of litigation as an alternative route to data access. In contrast, unsuccessful but determined researchers might consider doing so. The undersigned rejects petitioners' request to circumvent the data access protocols. Nothing in the statute suggests that Congress intended the Vaccine Program to be appropriated by researchers in this manner, or that such an outcome would serve the purpose of the Vaccine Program.

For the reasons more fully described in this Order, petitioners' Motion for Authority to Issue Subpoena, and Motion to Compel Access to the Vaccine Safety Data Link are **DENIED.** Petitioners' Motion for Pre-Payment of Expert Expenses is **DENIED** as moot.

VI. PETITIONERS' MOTION TO COMPEL PRODUCTION OF FDA DOCUMENTS

On March 2, 2012, petitioners filed a motion[44] seeking documents in the possession of the Food & Drug Administration (FDA)[45] related to the manufacturing method of concern to petitioners in this vaccine claim. Petitioners specifically requested documents containing any discussion of "the risk of DNA insertion or [the risk of] an allergic reaction to human tissue fragments" or demonstrating that the effect of residual "DNA was reviewed, studied or considered by the respondent or its agents." Pet'rs'

[44] Petitioners' Motion to Compel [Documents from the FDA], Mar. 2, 2012, ECF No. 50 (hereinafter "Pet'rs' MTC FDA").

[45] The FDA is an operating component of the U.S. Department of Health and Human Services, the respondent in this matter.

MTC FDA 5. Respondent responded[46] to petitioners' motion, and petitioners filed a reply.[47]

Pursuant to Vaccine Rule 7(a), petitioners first made an informal request for the documents. Discovery request, Jan. 31, 2012, ECF No. 50-1. Petitioners requested documents--that were generated as part of the FDA product licensing application process--for any vaccine, drug or cosmetic that uses human cell lines in the manufacture of the product. Id. 1-2. This application process would pertain to the MMR vaccine at issue in this matter, as well as to the varicella vaccine that is the subject of petitioners' motion to compel as addressed earlier in this order.

Respondent declined to provide the requested documents. Response to discovery request, Feb. 22, 2012, ECF No. 50-2. Respondent explained that petitioners had failed to establish that the discovery was either necessary or reasonable. Response to discovery request 1.

Petitioners clarified the scope of their earlier informal discovery request in their briefing of this motion to compel. Petitioners are seeking documents addressing the safety of the manufacturing process and the impact of specific residue on the safety of the finished product. Pet'rs' Reply re MTC FDA 2, 16. They are not seeking complete copies of the various applications. Id.

Petitioners now have narrowed their request to application materials for only the nine vaccines--as identified by Dr. Deisher--that are subject to the manufacturing method at issue in this case. Id. 1.

Petitioners' request is not limited, however, to any documents mentioning autism spectrum disorder, the claimed injury in this case. Id. 15. Rather, petitioners more broadly seek documents containing any discussion regarding the safety of the manufacturing process. Id.

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[46] Respondent's Response to Petitioners' Motion to Compel Documents from the Food and Drug Administration, June 14, 2012, ECF No. 65 (hereinafter "Resp't's Resp. to MTC FDA").

[47] Petitioners' Reply to Respondent's Opposition to Petitioners' Motion to Compel Production of Documents, July 14, 2012, ECF No. 69 (hereinafter "Pet'rs' Reply re MTC FDA").

A. Necessary

Petitioners bear the burden of showing that the discovery they seek is necessary for a proper evaluation of their claim. Pressed by respondent to explain why the requested discovery is necessary, petitioners responded by challenging the FDA's observance of recommended safety standards. Petitioners asserted that "presently available vaccines containing human DNA do not meet the safety standards recommended." Id. 12. Petitioners further asserted that the "literature establishes that [the] vaccines licensed by the respondent do not meet the safety criteria set by the respondent's advisory committees." Id. 2.

The literature to which petitioners cite, however, fails to support petitioners' allegations. Instead, as discussed in more detail below, the literature indicates that the cell lines used to manufacture both the MMR and varicella vaccines were found to produce safe and effective vaccines. See Pet'rs Ex. 59[48] at 190.

Although petitioners repeatedly state that they need respondent's comments about the applications, they do not explain why the information they seek is necessary.

Petitioners' particular claims are examined, in turn, below.

1. Petitioners' Allege that the FDA Failed to Follow Their Own Safety Standards

Petitioners make the stunning allegation that the FDA licensed the MMR and other vaccines in contravention of their "own safety criteria." Pet'rs' Reply re MTC FDA 2, 12. Petitioners contend that the discovery they seek is necessary because the court must understand the basis upon which such vaccines were licensed. Petitioners aver that the FDA licensed vaccines "for use on persons who are not being treated for a disease, including large numbers of well babies, that [did] not meet respondent's own safety criteria." Id. 2.

Pointing to the 2009 Sheng-Fowler article, petitioners insist:

> Old standards for safety are no longer relevant, as is pointed out most clearly by Li Sheng-Fowler, [who found] that the safety standards set by the FDA Vaccines and Related Biological Products Advisory Committee, i.e. <1 in 10^7 are not being met by vaccines. ***Th[e] authors [of the 2009***

[48] Li Sheng-Fowler, et al., Issues Associated with Residual Cell-Substrate DNA in Viral Vaccines, 37 Biologicals 190, 193 (2009) (Pet'rs' Ex. 59).

> ***Sheng-Fowler article] stated that '. . . the safety factors with respect to either DNA oncogenicity or DNA infectivity do not reach >10^7 when amounts of DNA alone are considered, ...' and therefore steps need to be taken to reduce the risk. Id. 193***. This [finding] indicates that presently available vaccines containing human DNA do not meet the [recommended] safety standards.

Id. 11-12 (emphasis added) (ellipsis in original) (citing Pet'rs' Ex. 59 at 193). Petitioners added that the information they seek would permit the court to evaluate the safety of certain licensed vaccines.

Petitioners rely solely on the 2009 Sheng-Fowler article to support their assertion that manufactured vaccines, including the MMR vaccine, do not meet FDA safety standards. However, a close review of the 2009 Sheng-Fowler article shows that, contrary to petitioners' claim, the article's authors expressed no safety concerns about the cell lines used in the production of either the MMR or varicella vaccines.

In the article, the authors "discuss[] potential risks associated with [the] use of novel highly tumorigenic neoplastic cells for the manufacture of viral vaccines, and [state that] any discussion about other types of cell substrates or products is beyond" the scope of the article. Pet'rs' Ex. 59 at 190. While the authors express concern about certain types of cell lines, their concern in no way applies to the cell lines used to manufacture either the MMR or varicella vaccines.

Although petitioners cite excerpted portions of the 2009 Sheng-Fowler article for the proposition that the vaccine manufacturing process in cell lines does not comport with FDA safety standards, the authors of the 2009 Sheng-Fowler article take the position that the cell lines used by the varicella vaccine, MRC5, and the rubella portion of the MMR vaccine, WI-38, are safe and effective. Id.; Deisher Expert Report ¶ 17.

> The variety of cell substrates that have been used for the manufacture of viral vaccines licensed in the United States is limited . . . **to the diploid cell lines (formerly termed diploid cell strains [1]) WI-38, MRC-5** . . . . **While these cell substrates have produced vaccines of proven safety and efficacy**, it is increasingly apparent that this repertoire is insufficient for the production of the next generation of viral vaccines, such as those against HIV/AIDS, against emerging infectious diseases (e.g., SARS) and against agents of bioterrorism.

Pet'rs' Ex. 59 at 190.

The literature to which petitioners cite indicates that the cell lines used in the manufacture of the MMR and varicella vaccines have produced vaccines of proven safety

and efficacy. Thus, petitioners' claim that the FDA failed to meet its own safety standards when licensing vaccines containing human DNA is wholly unsupported by any part of the record.

2. Petitioners Ask to Oversee the Work of the FDA

Petitioners contend that they are "entitled" to review FDA data on experiments so that they might make their own independent assessment of whether or not the data is valid. They argue:

> [T]he Respondent has custody or control of the material generated by the manufacture and by its own staff, used to analyze the threat to safety presented by the specific manufacturing process in issue, including laboratory tests. **This must include experiments of some sort to determine that the material in issue either does or does not create a hazard. The petitioner is entitled to review that data to determine its validity i.e. to subject it to the type of peer review required to establish a medical fact.**

Pet'rs' MTC FDA 11 (emphasis added).

But, as respondent correctly points out, "a retained expert's analysis of documents produced in the context of litigation is not akin to an objective 'peer review.' Nor can such a biased analysis 'establish a medical fact.'" Resp't's Resp. to MTC FDA 5. Petitioners here would appear to conflate improper litigation efforts and impartial scientific research.

Petitioners attempt to justify their request to review the FDA's work by suggesting that FDA conducted a particular type of test on the varicella vaccine prior to licensing, and that type of test--using nude mice--is insufficient to deem the vaccine safe.

> Should this type of test be all there is[,] that fact would show that there is no basis upon which to deem these vaccines safe, and that the incredible increase in autism spectrum diagnosis since the introduction of MMR II is more likely than not due to this manufacturing process, thereby confirming Dr. Deisher's opinion.

Pet'rs' Reply re MTC FDA 13.

But, the documents filed by petitioner in this case show that nude mice testing was not "all there is," and petitioners' expert, Dr. Deisher, was aware of this fact.

Petitioners have filed the FDA's Summary for Basis of Approval of the varicella vaccine, in support of Dr. Deisher's expert report. Pet'rs' Ex. 28. That summary prepared by the FDA provides information on "[a]dequately controlled studies supporting licensure," and identifies five different studies in which the varicella vaccine was administered to healthy children. Id. at 7-9.

In addition, the FDA's summary contains information about post-licensure studies that the vaccine manufacturer, Merck, agreed to conduct. Id. at 13. Aware of the Merck post-licensure studies, which failed to provide support for the theory advanced here, Dr. Deisher discussed them explicitly in her expert report.

> I must note that Merck did investigate the possibility of an immune response to the contaminating DNA and found no response – which is one of the reasons we have focused on the theory of genomic insertion. Merck's data may be meaningless; however, since the children would already have anti-DNA antibodies due to the earlier vaccines they received containing human DNA. However, I would think the six week data would show an elevation ….. which it did not. That said, unless we can see the actual MERCK raw data it is hard to tell if there was or was not an anti-DNA response in the subjects they evaluated. The conclusions are in the eye of the author, *i.e*. MERCK, unless the raw data is made available for others to examine. Unlike research scientists, manufacturers do not need to submit their results for peer review before it can be used to prove their conclusions.

Deisher's expert report ¶ 27 (citing Pet'rs Ex. 28 at 13) (ellipsis in original).

Again, petitioners have claimed support for their position by relying on documents that furnish no such support.

3. Petitioners Point to a Delay in Approving an HIV Vaccine to Call into Question the Safety of the Varicella Vaccine

Focusing on a discussion in the 1998 Kurth article of the difficulty in securing approval for a vaccine for HIV (human immunodeficiency virus), petitioners suggest that the identified issues concerning a prospective HIV vaccine, somehow, parallel the safety issues involved in the FDA's approval of the varicella vaccine, which is not the vaccine at issue in this matter. Petitioners argue that:

> [T]he assertion that the same advisory committee that set the < 1 in 10^7 safety standard approved the Varicella Vaccine which includes 2 ug of cellular DNA per dose of vaccine, needs to be explored. See [Pet'rs Ex. 28]. **It is also of note that this very issue is holding up approval of any vaccine for HIV.** See [Pet'rs' Ex.

> 54[49] at pp. 47-48]. This court cannot reach a credible conclusion without knowing the reasoning behind these decisions.

Pet'rs' Reply re MTC FDA 12 (emphasis added).

A review of the 1998 Kurth article cited by petitioners, however, shows that the expressed concerns, which are specific to retrovirus vaccines, do not apply to either the MMR or varicella vaccines. Pet'rs' Ex. 54 at 47-48.

> Retroviruses represent the only viruses that inevitably integrate almost at random into (preferably) DNAseI hypersensitive-sites of the human genome. . . . Because of their consistent chromosomal integration and the safety implications associated therewith (as discussed below) **it is highly unlikely that live attenuated retrovirus vaccines, for example, to protect against HIV, will be licensed**, at least not in the foreseeable future.

Id. (emphasis added).

Because neither the MMR vaccine nor the varicella vaccine is a retrovirus vaccine, petitioners' reliance on the 1998 Kurth article is unavailing, and petitioners' treatment of the cited literature does not lend credibility to their arguments.

4. Petitioners Seek Respondent's Comments on FDA Applications

Petitioners state–repeatedly–that they want the respondent's comments on the manufacturer's submissions, which petitioners regard as the "most critical documents sought." Pet'rs' Reply re MTC FDA 4.

> **[T]he comments of the respondent on such applications and their support is critical**. These submissions, their supports, the comments of the respondent's staff and all other considerations relating to safety are certainly necessary and reasonable to the determinations called for in this case.

Pet'rs' MTC FDA 7 (emphasis added). Petitioners add that:

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[49] R. Kurth, Risk Potential of the Chromosomal Insertion of Foreign DNA, in 93 Safety of Biological Products Prepared from Mammalian Cell Culture 45 (F. Brown et al., eds., 1998) (Pet'rs' Ex. 54).

> [T]he only place known where the relevance of this [manufacturing] phenomena to vaccines must have been reviewed is within the FDA. **There can be no question that the views of the respondent's staff on this phenomena at the time these applications were considered are material and necessary to any consideration of this theory, at this time**.

Pet'rs' Reply re MTC FDA 7-8 (emphasis added).

Petitioners' arguments indicate that petitioners very much want to know what, if anything, the respondent has said about the manufacturing method at issue here. This earnest desire for access to certain documents does not, however, make those documents necessary to a decision in this matter. Petitioners have not explained why these documents are necessary to the litigation of this matter, and the undersigned cannot discern the reason.

5. Petitioners Express Uncertainty About the Amount of Human DNA in the MMR Vaccine

Petitioners assert that the amount of human DNA in the MMR vaccine "cannot be obtained except from the manufacturer, a non-party, or from the respondent, a party," and that such evidence is "critical to this case." Id. 7.

Petitioners' theory of vaccine-related harm relies on the presence of human DNA in the MMR vaccine. Thus, evidence of the existence of human DNA in the MMR vaccine would be necessary to support petitioners' claim. It is not clear, however, that evidence of the amount of human DNA would be necessary as well, particularly because Dr. Deisher does not appear to have based her theory–that human DNA debris left in vaccines during the manufacturing process acts as a trigger for autism disorder–on the amount of human DNA contaminant in the vaccine.

Nonetheless, Dr. Deisher does seem to already have the information petitioners now seek. In her signed declaration, Dr. Deisher declared that a single dose of the "rubella component of the MMRII contain[s] approximately 200 nanograms [of] human fetal DNA," Deisher's MTC Decl. ¶ 10, although she provided no authority for this assertion. For the limited purpose of resolving this motion to compel, it is unnecessary to ascertain how Dr. Deisher determined that the MMR vaccine contains the cited amount of human DNA. But as the case moves forward, petitioners will need to furnish sound support for this assertion. [50]

[50] It is possible that the support for petitioners' assertion is Dr. Deisher's own evaluation of the MMR vaccine, see Pet'rs' Ex. 53; however, this is not clear from the filings.

6. Conclusion

Petitioners' theory is rife with numerous assumptions and inconsistencies that make it difficult to determine that any additional discovery is "necessary" at this time.

Discovery requests under the Vaccine Program cannot be construed to allow petitioners to appropriate for themselves the role of reviewing the FDA's work. Such a role is not contemplated by the Vaccine Program, and discovery for this purpose will not be granted.

Petitioners' unsupported claim that the FDA has failed to comply with its own safety standards before licensing the MMR and other vaccines is a serious charge that cannot be resolved in the context of this proceeding. More disturbing, however, is petitioners' effort to support their factual contention that "the literature establishes that vaccines licensed by the respondent do not meet the safety criteria set by the respondent's advisory committees," Pet'rs' Reply re MTC FDA 2, with a misleading partial quotation from the 1988 Kurth article. Because the evidentiary support for this factual contention is wanting, petitioners' counsel's compliance with Vaccine Rule 11(b) is called into question. An attorney who presents a signed motion or other paper to this court "certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances: . . . (3) **the factual contentions have evidentiary support** or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery." Vaccine Rule 11(b) (emphasis added).

Petitioners' motion does not appear to be a well-considered effort to meet their evidentiary burden under the Vaccine Program; but rather appears to be a brazen attempt to gain access to respondent's comments on the various vaccine licensing applications in the hope that something therein might be of relevance. As presented, there is nothing in petitioners' briefing or the record showing that the documents under FDA's control are necessary to a determination of the issues in this matter.

For the sake of completeness, the undersigned considers whether petitioners' discovery request is reasonable.

B. Reasonable

Petitioners take the position that "[w]here the information sought is material and necessary, burden is immaterial." Pet'rs' Reply re MTC FDA 16. The case law, however, counsels otherwise. The proper inquiry is whether production of the requested discovery is "reasonable" under all the circumstances--an inquiry which requires a balancing between the importance of the requested material to the fact finder and the burden imposed on the producing party or person. OAP, 2007 WL 1983780, at *7.

Respondent asserts that the burden of responding to petitioners' discovery request would be "extremely onerous and clearly outweighs petitioners' purported 'need' for the discovery." Resp't's Resp. to MTC FDA 7. As support for her position, respondent filed declarations from two current FDA employees, (1) Philip Krause, M.D., chair of the FDA committee that evaluated and recommended the varicella vaccine for licensure in 1995, see Krause Decl.[51] ¶ 3a; Pet'rs' Ex. 28 at 13-14, and (2) Joanne Binkley, a FDA deputy director who oversees the administrative division[52] "responsible for the disclosure of documents officially maintained by CBER," Binkley Decl.[53] ¶ 3, and who served as the lead on respondent's document production in the OAP during the mid-2000s, see Id. ¶ 2.

In connection with this motion to compel, Dr. Krause "reviewed copies of reviews associated with the original Varivax Product Licensing Agreement (PLA), including reviews related to the cells used to produce the vaccine and residual DNA in the vaccine." Krause Decl. ¶ 5. He declared that he has no knowledge of any "regulatory submissions or reviews related to a potential connection or evaluation of a potential connection between cell residuals (including DNA) and autism or autism-like illnesses." Id. ¶ 4.

Deputy Director Binkley discusses in detail the effort required by the FDA to produce the documents responsive to petitioners' request. She also provided an estimate of the number of responsive pages pertaining solely to the varicella vaccine, as well as the time and cost estimates to produce the documents to petitioners. Binkley Decl. ¶¶ 11-14. Deputy Director Binkley prepared this estimate on behalf of the FDA after reviewing petitioners' January 2012 request and their March 2012 motion to compel, with the understanding at that time, that petitioners sought the entire product licensure application for nine vaccines. Because petitioners now have clarified that they seek only part of the application, Pet'rs' Reply re MTC FDA 2, 16, Deputy Director Binkley's estimates are likely higher than revised estimates might be.

Petitioners assert that Deputy Director Binkley's declaration is "irrelevant" because it contains an overestimate regarding the anticipated burden of document production. Id. 16. But, petitioners dismiss too quickly the relevance of that declaration

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[51] Declaration of Philip Krause, M.D., June 12, 2012, ECF No. 65-1.

[52] FDA, Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach and Development (OCCD), Division of Disclosure and Oversight Management.

[53] Declaration of Joanne Binkley, June 12, 2012, ECF No. 65-2.

which provides a useful understanding of the work respondent would have to undertake to produce documents that are responsive to petitioners' request.

According to Deputy Director Binkley, to respond properly to a litigation-related document request, a FDA reviewer must: (1) search for and collect all potentially responsive documents from various central file locations; (2) conduct an initial review to verify that all documents are responsive to the request; and (3) redact the potentially responsive documents for certain categories of information that FDA regulations protect from public disclosure.[54] Binkley Decl. ¶¶ 7-8. Documents available only in hard copy would be scanned into electronic files, and as necessary, staff would discuss complex or novel disclosure issues with supervisors or the FDA's Office of Chief Counsel. Id. ¶ 7. The designated reviewer completes a quality control check to ensure that the responsive documents had been prepared properly for public disclosure. Id. The sponsor who provided the documents to the FDA--which in the case of the MMR and varicella vaccines is Merck--would be entitled to notification of the disclosure and an opportunity to review all documents to be disclosed and the FDA's proposed redactions. Id. ¶ 9 & n.2, ¶ 20. If the sponsor were to disagree with the proposed redactions, the FDA would attempt to reach an agreement. Id. ¶ 9. If no such agreement could be reached, Deputy Director Binkley reports that the sponsor could seek to intervene in this case. Id. Finally, the designated reviewer would prepare copies of the responsive documents for delivery to petitioners by numbering (bates-stamping) each page. Id. ¶ 8. If necessary, a privilege log would be prepared as well. Id.

Deputy Director Binkley estimates that after an initial identification of the responsive documents, a review taking about eight minutes per page would be required. She acknowledged that additional time might be required for electronic redactions. Id. ¶ 12.

Petitioners argue that the burden on the respondent to produce, "all the documents related to varicella" cannot be that great because within a three-month period of time after petitioners filed this motion to compel, the FDA was able to locate and review those documents, and Dr. Krause was able to "review, consider and write a declaration as to all

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[54] Respondent explains that FDA regulations exempt certain types of information from public disclosure. Information subject to redaction includes trade secrets, confidential commercial information, personal identification information, and information concerning the deliberative process. Resp't's Resp. to MTC FDA 3 n.1 (citing 21 U.S.C. § 331(j); 18 U.S.C. § 1905; 21 C.F.R. §§ 20.61 - 20.63). FDA regulations further provide that the agency will make such records available in compliance with a final court order. 21 C.F.R. § 20.83(a). Any order issued by this court would be unlikely to compromise the protection accorded to confidential business information and thus, would allow FDA to redact the produced documents.

the documents related to varicella . . . ." Pet'rs' Reply re MTC FDA 15-16. Petitioners conclude that the material sought as to the varicella vaccine is "apparently readily available . . . on or near Dr. Krause's desk," and thus should pose no burden for the respondent to produce to petitioners. Id.

Petitioners have misunderstood the scope of Dr. Krause's review. Dr. Krause never represented that he had reviewed all the documents related to the varicella vaccine. Rather, he stated that he had "reviewed copies of reviews associated with the original Varivax Product Licensing Agreement ("PLA"), including reviews related to the cells used to produce the vaccine and residual DNA in the vaccine." Krause Decl. ¶ 5 (emphasis added). While petitioners are correct that Dr. Krause did review documents prior to preparing his declaration, he did not review all of the documents related to the varicella vaccine.

Although the undersigned is unable to estimate, with precision, the time and cost burden to respondent, the undersigned is persuaded that the burden imposed on respondent to respond to petitioners' would be a significant one.

According to Dr. Deisher, the change in the manufacturing process for the MMR vaccine occurred in 1979. Deisher's expert report ¶ 20. The MMR application file is thus more than 30 years old.

The varicella vaccine was approved in 1995, and the FDA's Summary for Basis of Approval reports that experiments were conducted 1982, 1984, 1987, and 1991--but whether each version of the varicella vaccine was manufactured with the process at issue is uncertain. Pet'rs' Ex. 28 at 7-9. The varicella application file is between 20 and 30 years old.

Deputy Director Binkely estimates that just less than half of the responsive pages for the varicella vaccine (the entire application, not just the part petitioners seek) were submitted electronically. Binkley Decl. ¶ 13. Thus, because a substantial proportion of responsive documents exist only in hard copy form, they would have to be scanned into electronic file format for production to petitioners.

As described, the efforts required of the FDA to review nine separate vaccine application files to locate the particular portions that are responsive to petitioners' current request would be quite burdensome. The applications are more than 20 years old and a significant portion of each application, judging from the varicella application, seems to exist currently in a paper format only. The FDA reviewers would have to: (1) conduct a page by page review of the responsive portions of the application, and (2) search for confidential business information or other information subject to redaction under the FDA regulations. Further review within the FDA of the proposed redacted, responsive documents would occur, and Merck would likely exercise its right to review as well. It is

clear on this record that even if there were no disagreement about which documents are responsive or which redactions are justified--this production effort would be a time consuming, labor intensive process. Such effort is not a reasonably imposed burden.

Were the discovery found to be necessary, which it has not been, perhaps respondent would need to provide an updated estimate of the production volume, given petitioners' narrowed request. On this record, however, this is unnecessary.

For the reasons detailed above, Petitioners' Motion to Compel production of documents from the FDA is **DENIED**.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Chief Special Master